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SUPREME COURT OF THE UNITED STATES

OCTOBER TERM, 1958

No. 27

MARION B. FOLSOM, SECRETARY OF HEALTH, EDUCATION AND WELFARE, PETITIONER,

vs.

FLORIDA CITRUS EXCHANGE, FRANK R. SCHELL, ET AL.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

PETITION FOR CERTIORARI FILED JANUARY 3, 1958

CERTIORARI GRANTED MARCH 17, 1958

SUPREME COURT OF THE UNITED STATES

OCTOBER TERM, 1957

No. 703

MARION B. FOLSOM, SECRETARY OF HEALTH, EDUCATION AND WELFARE, PETITIONER,

vs.

FLORIDA CITRUS EXCHANGE, FRANK R. SCHELL, ET AL.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

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[fol. a]

IN UNITED STATES COURT OF APPEALS, FIFTH JUDICIAL CIRCUIT

Pleas and Proceedings had and done at a regular term of the United States Court of Appeals for the Fifth Circuit, begun on the first Monday in October, A. D., 1956, before the Honorable Joseph C. Hutcheson, Jr., Chief Judge, the Honorable Warren L. Jones and the Honorable John R. Brown, Circuit Judges:

No. 15934

FLORIDA CITRUS EXCHANGE, et al., Petitioners,

vs.

M. B. FOLSOM, Secretary of the Department of Health, Education and Welfare, Respondent

and

No. 15948

FRANK R. SCHELL, Petitioner,

vs.

M. B. FOLSOM, Secretary of the Department of Health, Education and Welfare, Respondent

Be It Remembered, That heretofore to-wit, on the 21st day of August, A. D., 1956, a consolidated transcript of the record in the above styled causes, pursuant to petitions for review of orders of the secretary of Health, Education and Welfare was filed in the office of the Clerk of the said United States Court of Appeals for the Fifth Circuit, in Volumes I & II; the petition for review in cause 15934 was filed and docketed on February 2, 1956, and the petition for review in cause 15948 was filed and docketed on February 8, 1956, as follows, to-wit:

[fols. 1-13] IN THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

No. 15934

FLORIDA CITRUS EXCHANGE, et al., Petitioners on Review,

vs.

M. B. FOLSOM, Secretary of the Department of Health, Education and Welfare, Respondent on Review

PETITION OF FLORIDA CITRUS EXCHANGE AND OTHERS FOR JUDICIAL REVIEW OF AN ORDER OF THE SECRETARY OF HEALTH, EDUCATION AND WELFARE, DATED NOVEMBER 10, 1955, F. R. DOC. 55-9209—FILED NOVEMBER 15, 1955

U. S. Court of Appeals, Filed February 2, 1956, John A. Feehan, Jr., Clerk.

[fols. 14-15] To the Honorable Judges of the United States Court of Appeals for the Fifth Circuit:

Florida Citrus Exchange, a cooperative under the laws of the State of Florida, embracing a membership of forty-four packing houses; Haines City Citrus Growers Association, a cooperative under the laws of the State of Florida; Waverly Growers Cooperative, a cooperative under the laws of the State of Florida; Herman J. Heidrich, Paul D. Heidrich and Francis X. Heidrich, a co-partnership doing business as Herman J. Heidrich & Sons, residents of and having their principal place of business in Florida; Snively Groves, Inc., a corporation under the laws of the State of Florida; Donna Fruit Company, a corporation under the laws of the State of Texas; J. Floyd Hetrick and Harlow C. Richardson, a co-partnership doing business as Hetrick & Richardson; Horace Etchison, Foy G. Hall and Joseph M. Allex, a co-partnership doing business as McAllen Fruit and Vegetable Company, Roy Weir, Mrs. I. M. Weir and J. H. Williams, a co-partnership doing business as Valley Fruit Company, all being residents of and having their principal place of business in the State of Texas, present this petition for Judicial review of an order entered by the

Secretary of Health, Education and Welfare and, in support thereof, respectfully represent as follows:

I

The Nature of the Proceedings

The corporations, cooperatives, associations, partnerships and individuals named in the preceding paragraph, and hereinafter referred to as Petitioners, seek Judicial review of an order of the Secretary of Health, Education [fol. 16] and Welfare, dated November 10, 1955 (F. R. Doc. 55-9209, filed November 15, 1955) and published in the Federal Register under date of November 16, 1955, pages 8492-8495, both inclusive, with the heading,

Title 21—Food and Drugs Chapter 1—Food and Drug Administration, Department of Health, Education and Welfare.

Part 135—Color Certification.

Miscellaneous Amendments.

This order was entered by the Secretary of Health, Education and Welfare under the provisions of the Act of June 25, 1938 (a) 675 paragraph 406, 52 stat. 1049, reorg. plan No. IV, par. 12 effective June 30, 1940, 5 F.R. 2422, 54 stat. 1237, 21 U. S. Code An. Sub-paragraph 346 (b) provides:

"The Secretary shall promulgate regulations providing for the listing of coal-tar colors which are harmless and suitable for use in food and for the certification of batches of such colors, with or without harmless diluents Title 21 USCA page 209.

Petitioners filed their exceptions and briefs in opposition to the order. The order deleted FD&C Red #32 and the action affecting these petitioners appears in paragraph 5 of the conclusions.

II

Jurisdiction of the Court

The Court has jurisdiction by virtue of the Federal Food, Drug and Cosmetic Act (Public Law 717—75th Congress, Chapter 675—3rd session) Act of June 25, 1938, 52 Stat. 1055 and amendments thereto, 21 U.S.C.A. 371,

and the Administrative Procedure Act, Act of June 11, 1946, 60 stat. 243, title 5 U.S.C.A. 1009.

[fol. 17] III

Facts and Statutes Upon Which Jurisdiction is Based

1. All these petitioners who are natural persons reside in the Fifth Circuit; all those who are partnerships are residents of and have their principal place of business in the Fifth Circuit; and all those that are corporations have their places of business in the Fifth Circuit.

2. An actual controversy exists as to the validity of the order hereinbefore and hereinafter referred to and all these petitioners will be adversely affected by such order if placed in effect and all of them are adversely affected and aggrieved by the action of such agency entering the order and all are entitled to have the order reviewed by judicial review under the statute referred to in Paragraph II.

3. Your petitioners are engaged in the packing and marketing of oranges, and some are also growers of oranges, some in the State of Florida and some in the State of Texas; they are all users of dye FD&C Red No. 32 for the coloring of oranges and have been such users for many years; that they, together with many others similarly situated, have large sums of mon-y invested in the equipment for the coloring of oranges with FD&C dye Red No. 32 and that such dye has been in common usage for the coloring of oranges since before 1938.

4. That the United States Department of Agriculture recognizing that oranges mature and fully ripe, still remained [fol. 18] green on the outside encouraged and approved the coloring of fully mature oranges and over the years a market has been developed whereby the public buys the colored oranges much more readily than it would those greenish in color even though fully mature.

5. That in 1939 the Department of Agriculture, which Department had at that time jurisdiction of the Food, Drug and Cosmetic Act, after extensive studies and hearing certified FD&C Red No. 32 as "harmless and suitable for use in the coloring of foods", and since that time more than 59 per cent of all the oranges shipped in Florida and a large percent in Texas have been colored with said dye;

that FD&C Red No. 32 is now used solely for the coloring of oranges and that there is no other certified color available.

6. That the laws of both Florida and Texas have been standards requiring maturity before shipment; that the laws of the State of Florida only allows coloring upon oranges that have greater standards of maturity than uncolored oranges; that oranges must meet the U. S. and State standards as to grade and pack and such color cannot be used to cover inferiority; that the coloring matter FD&C Red #32 is harmless and is particularly adapted to the coloring of oranges and is not harmful in the manner and quantity used; that the effect of the order would be to demoralize the orange market, to greatly reduce prices, to disrupt trade practices that have been in existence for many years and in many instances make it practically impossible to sell oranges because the public has been educated to buy oranges with an orange coloring, and would [fol. 19] result in irreparable injury and get financial loss to these petitioners and the orange growers of Florida and Texas impossible to measure in dollars and cents, that at certain seasons of the year it is practically impossible to sell uncolored oranges because the orange is one of the very few fruits that has blossoms, small fruit and fully ripe and mature fruit on the tree at the same time, that when the chlorophyll (green color) rises in the tree to go into the leaves and new fruit it likewise goes into the mature and ripe fruit "regreening" it, causing it to be green on the outside when it is mature, and by reason of this it is practically impossible to sell unless colored. This caused the Industry and the United States Department of Agriculture to spend vast sums in research. The color method using FD&C Red #32 was developed, approved and certified as "harmless and suitable for use in food" and at the time of the hearing had been used in coloring of more than two hundred and fifty six million boxes of oranges, and since the hearing additional to bring the total to in the neighborhood of three hundred million boxes being more than half or all fresh oranges shipped and in some areas and in some of the petitioners packing house 100% of all oranges shipped are so colored, without any harmful effects to any human.

7. The order will deny to petitioners the use of the only dye now available for use in the coloring of oranges, which is the color that has been certified for 17 years.

The Order was entered and published in the Federal Register under date of November 16th, 1955, and will take effect 90 days from that date (February 14, 1956), unless stayed or suspended by this Honorable Court.

[fol. 20] IV

Points on Which Petitioners Intend to Rely

In this petition for Judicial review of the order insofar as it relates to FD&C Red #32, petitioners intend to rely on the following points among others:

1. The order is illegal and erroneous and based upon the Secretary's erroneous construction of the law, taking the position that there must be zero toxicity and that a coal-tar color containing a harmful ingredient is per se harmful and not harmless notwithstanding the quantity and manner of use. This interpretation is contrary to the construction of the word "harmless" as intended in the passage of the Act, the record showing that only four parts per million of coloring matter applied on the outer rind, not even penetrating the rag, and that juice extracted from color-added oranges contains only 0.07 parts per million of coloring matter, whereas the Congressional hearings the then head of the Food, Drug and Cosmetic Department sponsoring the legislation informed the Committee in the House of Representatives:

"There are very few things in which you will not find contaminating products in some degree."

The Senate hearings show the toxic contents of fish, cod-liver oil and other named foods far in excess of the coloring matter applied to oranges and that the toxic ingredients in shrimp and prawn were 30 parts per million (7½ times all the coloring matter on an orange and more than 420 [fol. 21] times the amount of coloring matter found in the juice extracted from color-added oranges.)

2. The order is arbitrary and illegal because the tests and the findings on which same are based are unrealistic and have no relation to the methods and manner in which

FD&C Red #32 is used on oranges. The report showed no adverse effect when fed at the lowest level selected for that purpose and these levels were in excess of the amount of color likely to be ingested under normal usage.

3. The order and the findings on which it is based are erroneous and arbitrary in that they did not take into consideration the use to which the color is to be used and the record showing that in the ratio of the amounts fed to rats and dogs as compared to human beings it is not harmful to human beings and is not harmful in the manner and quantity in which it is used.

4. The order is arbitrary and unlawful because it ignores the undisputed testimony in the record that the amount of dye and the amount and method of proposed use was necessary to determine whether it was harmless. This method of testing and evaluating was not followed even though the record shows that FD&C Red #32 is only used for the coloring of oranges, that it is the only color certified for use used for coloring oranges and that it is harmless in the manner and quantity it is used, and that the legislative history of the Act show- that it was known and intended in the passage of the Act that coal-tar colors were to be used in the coloring of oranges.

[fol. 22] 5. The record contains no substantial evidence to warrant the order deleting Dye FD&C Red #32 for the coloring of food and particularly the coloring of oranges.

6. The Order ignores the record which shows that there is no data as to whether the color is or is not harmless for external application and ignores the record which shows affirmatively that FD&C Red #32 in the manner and quantity applied to oranges has no harmful effects. And the order is arbitrary, unlawful and capricious in that it construes the word "harmless" in an unreasonable manner and contrary to that intended by Congress in the passage of the Federal Food, Drug and Cosmetic Act.

7. The order is based on an unrealistic test, the feeding to the test animals was many times that which would be ingested by man under normal usage or under any reasonable condition or in the manner and quantity in which the color is used.

8. The Order is not based on the whole record and erroneously disregards substantial evidence of record.

9. The Secretary has mis-interpreted the law and erroneously takes the position that if there is any harmful ingredient in the coal-tar color that it is not harmless and cannot continue to be certified even though the record shows and it is admitted that it is harmless in the manner and quantity as used in the coloring of oranges. This is an arbitrary and strained construction and not a reasonable construction and ignores the decision of the United States Supreme Court in the case of Lexington Mill and Elevator Co. 232 U. S. 339, 58 Law Ed. 658 wherein The Court said: [fol. 23] "In recognizing that small quantities of arsenic is not injurious to health, the government acknowledges that this term is a relative one. Arsenic is found in infinitesimal quantities in so many articles of food that it has been said that the air we breathe, the water we drink, the smoke and dust we inhale, and all the foods we consume contain arsenic. If the terms be an absolute one, then they would all be condemned. The quantity of arsenic found in this color material is so infinitesimal that, when diluted as it is ordinarily used, it would take years to produce 'a dose' such as is ordinarily prescribed by physicians—one-thirtieth of a grain. In other words, one would be required to drink 150,000 bottles of soda before he would have consumed a quantity of arsenic sufficient to equal the 'dose'. . ."

10. The Order is erroneous for the reason that the record affirmatively show- that the tests were made upon two ingredients and that it is not shown that they were of satisfactory purity as to freedom from harmful substances when they were received or tested. It not being shown even that the ingredients were received from commercial firms ordinarily engaged in preparing FD&C Red #32.

11. The Order and the findings are not based upon substantial testimony, and are arbitrary, capricious and in excess of the Secretary's power under the law, and illegal for other reasons apparent upon a review of the record.

12. The Order takes an erroneous construction of the law, taking the position that the Secretary cannot certify for restricted use in coloring foods and based on the erro- [fol. 24] neous belief that the color must be harmless when used in all goods. This is contrary to the law and contrary to the basic concept on which the color was certified. The

record of that hearing shows the position of the Chief of the Pharmacology Division F.D.A. When FD&Red #32 was certified in 1939 (21 CFR 135.3) as harmless and suitable for use in food, his statement being:

(Dr. Calvery.) "No, in my opinion there are no coal-tar colors that are harmless and suitable for use in all kinds and classes of Foods, Drugs and Cosmetics. . ."

"Yes, by harmless and suitable for use for purposes indicated, we mean that in the concentrations that these substances are used for coloring purposes, it is our opinion that no harm can come from them to the user when used in the concentrations for which they are designed and for the purposes for which they are designed. . ."

(U.S.D.A.—FD & C #4, Feb. 7, 1939, page 228)

V

Prayer for Relief

Wherefore, Petitioners hereinbefore named cause this Petition to be signed in their behalf by their undersigned attorney and petitioners respectfully pray that this Honorable Court grant a review of the proceedings resulting in the order of the Secretary of Health, Education and Welfare, dated November 10, 1955 as hereinbefore referred to and the order itself; that a copy of this Petition and the [fol. 25] Petition for Stay be transmitted to the Secretary of Health, Education and Welfare of the United States; and that the Secretary be required to certify and file with this Court a transcript of the record upon which the said order was entered as required by law; and that upon such review the above described order be set aside insofar as it relates to FD&C Red #32 and held for naught; that this Court enter an order setting aside temporarily and staying the taking effect of the order of the Secretary of Health, Education and Welfare insofar as it relates to the use of FD&C Red #32, until the final determination of the petition for review in this case; that this Honorable Court enter a stay order, injunction or any and all necessary and appropriate process to postpone the effective date of the Secretary's order insofar as it relates to FD&C Red #32 and to preserve status or rights of these petitioners

pending conclusion of the review proceedings, or; if the Court in its discretion, should determine that the relief prayed for hereinbefore should not apply to the entire order insofar as it affects FD&C Red #32, then petitioners pray that the Honorable Court grant a stay order or other orders staying the operation of the Secretary's order insofar as it relates to the use of FD&C Red #32 for the coloring of mature oranges, when harmless in the manner and quantity as used; and that Petitioners may have such other and further relief as the allegations herein may warrant and as to the Court may seem meet and proper.

Dated January 30, 1956.

(S.) J. Hardin Peterson, Attorney for Petitioners on Review.

Cochrane Building, Lakeland, Florida.

[fol. 26] IN THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

No. —

FLORIDA CITRUS EXCHANGE, et al., Petitioners on Review,

vs.

M. B. FOLSOM, Secretary of the Department of Health, Education and Welfare, Respondent on Review.

PETITION FOR STAY OF ORDER OF THE SECRETARY OF HEALTH, EDUCATION AND WELFARE—Dated January 30, 1956.

To the Honorable Judges of the United States Court of Appeals for the Fifth Circuit:

Florida Citrus Exchange, a cooperative under the laws of the State of Florida, embracing a membership of forty-four packing houses; Haines, City Citrus Growers Association, a cooperative under the laws of the State of Florida; Waverly Growers Cooperative, a cooperative under the laws of the State of Florida; Herman J. Heidrich, Paul D.

Heidrich and Francis X. Heidrich, a co-partnership doing business at Herman J. Heidrich & Sons, residents of and having their principal place of business in Florida; Snively Groves, Inc., a corporation under the laws of the State of Florida; Donna Fruit Company, a corporation under the laws of the State of Texas; J. Floyd Hetrick and Harlow C. Richardson, a co-partnership doing business at Hetrick & Richardson, Horace Etchison, Foy G. Hall and Joseph M. Allex, a co-partnership doing business as McAllen Fruit and Vegetable Company, Roy Weir, Mrs. I. M. Weir and J. H. Williams, a co-partnership doing business as Valley [fol. 27] Fruit Company, all being residents of and having their principal place of business in the State of Texas, hereinafter referred to as Petitioners, who are concurrently filing with the Court a Petition in the above entitled cause for Judicial review of an order dated November 10, 1955 and to become effective on the 14th day of February, 1956, present this Petition to stay the order of the Secretary referred to above pending Judicial review and in support of this petition respectfully represent and allege the following:

I

The Petition for Judicial Review

The Petition for Judicial Review filed concurrently with this petition is incorporated in this petition by reference. The Court is respectfully urged to read the Petition for Judicial Review and before reaching a conclusion on this petition for a stay order.

II

The Applicable Statutes

Sec. 70 (f) (3) Federal Food, Drug and Cosmetic Act (Act of June 25, 1938, 52 Stat 1056, 21 U.S.C.A. Par 371, (f) (3), page 238 provides as follows:

"The Court shall have jurisdiction to affirm the order or to set it aside in whole or in part, temporarily or permanently."

The Administrative Procedure Act, Act of June 11, 1946, 60 Stat 243, title 5, par. 1009 U.S.C.A. appearing as part of

[fol. 28] subparagraph (d) of par. 1009 page 464 U.S.C.A. Provides as follows:

"Upon such conditions as may be required and to the extent necessary to prevent irreparable injury, every reviewing Court (including every Court to which a case may be taken on appeal from or upon application for certiorari or other writ to a reviewing Court) is authorized to issue all necessary and appropriate process to postpone the effective date of any agency action or to preserve status or rights pending conclusion of the review proceedings."

III

Statement of Cause

The petitioners respectfully refer to their petition for review as part of the cause is recited therein and, in addition thereto would show as follows:

That the Food, Drug nd Cosmetic Act required the certification of coal-tar colors that were "harmless and suitable for use in food", that pursuant to that authority coal-tar dye designated as FD&C #32, which has been temporarily certified and which had been used prior to the permanent certification was certified in 1939 as "harmless and suitable for use in food" (21 CFR 153.3); that petitioners are the operators of packing houses packing oranges and a number of them are growers of oranges and all now use and have been using said color for a number of years. Petitioners ship several million boxes of color-added in bringing this suit, and that the packers using this color for oranges and packing more than 88 per cent of the [fol. 29] oranges so colored, joined in the exceptions to the Secretary's order and it is only for convenience that they are not named herein. These petitioners, pack a number of million boxes each year and it is necessary to color with this color a high percentage of the oranges shipped by them, some of these petitioners having to color all of the oranges shipped by them with the use of this color and all of the shippers coloring a substantial amount.

That under date of November 10, 1955, Secretary of Health, Education and Welfare entered an order deleting this color from the certified list. This is the only

color certified for the coloring of oranges and when color added is referred to herein it means FD&C Red #32.

This order will result in irreparable injury to petitioners and each and all of them and denies to them the only dye now certified and suitable for use in coloring oranges and the purpose of this proceeding is to stay the taking effect of the Order of the Secretary until the final determination of the Petition for review by the Court.

IV

Reasons in Support of a Stay Pending Judicial Review

The Secretary's Order will go into effect on February 14, 1956 unless it is stayed. Unless it is stayed irreparable injuries will result to the petitioners and each and every one of them, some details of which are hereinabove set [fol. 30] forth; that the granting of the stay will not be against the public interest and will not affect the public health but will result in keeping the status quo of the matter as it has been for around 17 years without any injury to the public.

The Department of Health, Education and Welfare does not take the position that the use of this color is harmful when used in the coloring of oranges but takes the position that only harmless colors are eligible for certification and that the FD&C Red #32 cannot continue to be certified for use though it is admitted that it is harmless in the manner and quantity in which it is used in the coloring of oranges.

In a letter dated February 7, 1955 when the question of decertification was pending the Commissioner of the Food and Drug Administration, George P. Larrick, advised officially:

"There is, however, no evidence that in the amounts used and in the manner of use, in the coloring of citrus fruit the product so colored is not safe for human consumption."

(Letters to Honorable Spessard L. Hollard, U.S. Senator, Honorable George E. Smathers, U.S. Senator, and Honorable James A. Haley, Member of Congress), copy

of one of these letters attached as exhibit A and made a part hereof.

That it is necessary in order to market certain varieties of early oranges and certain varieties of late oranges that they are colored. The Department of Agriculture has long recognized this and as early as 1932 in the [fol. 31] U.S. Department of Agriculture annual report, excerpts from which were filed in the hearings on the Food, Drug and Cosmetic Act in 1935, and the Department of Agriculture Year Book for 1932, pages 134 to 137 states:

"Some of the early fall varieties of oranges and grapefruit ripen while the fruit is still green in color. Later varieties that mature in the spring or summer assume the color of full maturity during the winter while the fruit is still immature, but when warm spring weather occurs the rind may turn green again. Thus, while the edible part of the fruit ripens there is a 'regreening' of the rind. . ."

"Grapefruit growing inside densely foliated trees never develops full color, although some of the best-flavored fruit is produced there. There is, therefore, no definite relation between flavor or maturity and the color of the fruit while on the tree. However, there is a very significant relation between the color of the fruit offered for sale and the price that it will bring, and citrus fruit producers have always faced the problem of making the color of ripe fruit match its flavor."

Excerpts from U. S. Department of Agriculture Bulletin 1159 filed in hearings on Food and Drug Legislation (Hearings H of R 1935 pp. 172-189) had this to say:

"It is well known that citrus fruits grown under certain climatic and cultural conditions may be mature and highly desirable for food while the skin of the fruit is still green in color. . ."

[fol. 32] "On the other hand, green-colored fruit, no matter what the quality, is difficult to merchandise. In the mind of the consuming public a green-colored orange is immature and unfit for food. The public desires fruit for decorative purposes as well as for eating, and a well-

colored orange is much more attractive than one green or partially green in color. It is evident, then, that some method of treating this fruit so that it would assume a rich orange yellow color early in the season, when it is most desirable for food, would be of benefit to the industry and to the consuming public alike."

Under the State law color is only allowed upon mature oranges and in Florida a greater standard is required for coloring than for other oranges. It is necessary to color in order to sell at a fair price. The late variety of oranges are already beginning to re-green as the Spring growth comes into the tree and it would be impossible to sell many of the Valencias at any price at all or others at vastly reduced prices unless they are colored. This will result in the loss of many millions of dollars to the petitioners and many other growers and packers similarly situated and will cause unemployment to those engaged in the picking and packing of fruit and will cause irreparable injury impossible to measure in dollars and cents to these petitioners and each of them. To stay the order would not be detrimental to the public interest. Around three hundred million boxes of color-added oranges have been shipped without injury to human beings. This is around 59% of all oranges shipped since the certification of the dye. The amount used of coloring matter is very minute, only 4 parts per million appied on the outside of the rind. This is less than the toxic [fol. 33] matter contained naturally in shrimp, prawn, cod liver oil, fish, and a number of other foods. The dye is oil soluble and does not even penetrate the rag of the orange. No harm would result in the granting of the stay and great and irreparable injury would result to petitioners and to many other if the Order delisting FD&C Red #32 takes effect.

V.

Prayer for Relief

Wherefore, Petitioners hereinbefore named cause this Petition to be signed in their behalf by their undersigned attorney and petitioners respectfully pray that this Court

enter an order setting aside temporarily and staying the taking effect of the order of the Secretary of Health, Education and Welfare insofar as it relates to the use of FD&C Red #32, until the final determination of the petition for review in this case; that this Honorable Court enter a stay order, injunction or any and all necessary and appropriate process to postpone the effective date of the Secretary's order insofar as it relates to FD&C Red #32 and to preserve status or rights of these petitioners pending conclusion of the review proceedings, or: if the Court in its discretion, should determine that the relief prayed for hereinbefore should not apply to the entire order insofar as it affects FD&C Red #32, then petitioners pray that the Honorable Court grant a stay order or other orders staying the operation of the Secretary's order insofar as it relates to the use of FD&C Red #32 for the coloring of mature oranges, when harmless in the manner and quantity as used; and that Petitioners may have such other [fol. 34] and further relief as the allegations herein may warrant and as to the Court may see- meet and proper.

Petitioners have appended hereto a copy of the Order and Exhibit "A".

Dated January 30, 1956.

J. Hardin Peterson, Attorney for Petitioners on Review.

Cochrane Building, Lakeland, Florida.

AFFIDAVIT

STATE OF FLORIDA,
County of Polk:

Personally appeared before me, J. Hardin Peterson, who being duly sworn deposes and says:

That he is attorney for petitioners in the above cause and that he prepared and read the foregoing petition and that the allegations contained therein are true; that in addition to being attorney as aforesaid that he is an orange grower, and has been for 30 years or more and served as attorney for the Florida State Department of Agriculture; that he is attorney for a large segment of citrus packing houses, that he has followed the problem of coloring

oranges for many years and is familiar with the problem; that based upon his knowledge and experience that the putting into effect of the Order of the Secretary would cause irreparable loss to petitioners and would be an impact on the citrus industry that would cause great and [fol. 35] vast loss to many others; that the petition is filed in good faith.

J. Hardin Peterson.

Sworn to and subscribed to before me this 30th day of January, 1956.

Frances M. Linsner, Notary Public, State of Florida.
(Seal.)

My commission Expires: April 4, 1959. Bonded by American Surety Co. of N. Y.

CERTIFICATE OF SERVICE (omitted in printing)

AFFIDAVITS AS TO PETITIONS

STATE OF FLORIDA,
County of Polk:

Personally appeared before me John A. Snively, who, being duly sworn deposes and says that he is President of Snively Groves, Inc. and that the allegations in the Petition for Review hereinbefore set forth are true, and that said Petition is filed in good faith.

(S.) John A. Snively.

[fol. 36] Sworn to and subscribed to before me this 31st day of January, A. D. 1956.

(S.) Ruby Snead, Notary Public, State of Florida At Large.

My Commission Expires: March 23, 1957.

STATE OF FLORIDA,
County of Polk:

Personally appeared before me, John A. Snively who, being duly sworn, deposes and says that he is President of Snively Groves, Inc., one of the Petitioners in the foregoing

petition for stay and that the allegations of said petition for stay are true; that this company has shipped many millions of boxes of oranges using FD&C Red #32 for coloring, without any harmful effects and that it is at present a user thereof, and that to deny the use of this dye will make it practically impossible to market oranges without coloring and will result in great loss, impossible to definitely measure in dollars and cents and will result in irreparable injury to this Petitioner and many others.

(S.) John A. Snively.

Sworn to and subscribed before me this 31st day of January, A. D. 1956.

(S.) Ruby Snead, Notary Public, State of Florida At Large.

My Commission expires: March 23, 1957.

[fol. 37] IN UNITED STATES COURT OF APPEALS

EXHIBIT "A" TO PETITION

Department of Health, Education, and Welfare, Food and Drug Administration, Washington 25, D. C.

Feb. 8, 1955.

Honorable James A. Haley, U. S. House of Representatives.

DEAR CONGRESSMAN HALEY:

In response to your request we have prepared this statement with regard to the coloring of citrus fruit.

As is stated in the enclosed reprint from the Federal Register of December 30, 1954, we recently proposed the amendment of the Color Certification Regulations to delete the colors designated as FD&C Orange No. 1, FD&C Orange No. 2, and FD&C Red No. 32. The date for receiving objections and comments on the proposal has been extended to include March 7, 1955. No final action will be taken on this proposal until some time after that date. The proposal is based upon evidence adduced at a recent hearing

which indicates that these colors are not harmless for use in food within the meaning of Section 406 of the Federal Food, Drug, and Cosmetic Act, as was previously believed.

Pending our further consideration of this matter and the final determination thereon and the issuance of new color certification regulations, no ban is placed on the use by the citrus industry of the colors designated above or on the sale and shipment of color-added citrus fruit.

FD&C Red No. 32 is the color tha has been generally used in the coloring of oranges.

[fol. 38] The proposal to remove these coal-tar colors, including FD&C Red No. 32, from the list of colors eligible for certification for use in food results from the requirement of the Pure Food Law that only colors that are harmless are eligible for certification. Recent investigations show that these colors when fed in substantial amounts, show evidence of toxicity. There is, however, no evidence that, in the amounts used, and in the manner of use, in the coloring of citrus fruit, the product so colored is not safe for human consumption.

Sincerely yours, (S.) Geo P. Larrick, Commissioner of Food and Drugs.

Enclosure.

FR Rep 12-30-54 re color. Feb. 8, 1955.

Final Order of Secretary of Health, Education and Welfare, dated November 10, 1955 Omitted hereinafter copied at page 158.

AFFIDAVIT

STATE OF NEW YORK,
County of New York:

Personally appeared before me, R. D. Gerwe, who, being duly sworn, deposes and says:

[fol. 39] That he is Head of the Research Department of the Food Machinery and Chemical Corporation; that he has had a broad education and experience in the matter of food, food chemistry and food colors and matters relating

to oranges and the coloring matter used on oranges; that his background of education is as follows:

B. S. Miami University, Oxford, Ohio, 1927.
M. A. University of Cincinnati, 1929.
Ph. D. University of Cincinnati, 1932.
Instructor in Chemistry, Oxford College, Oxford, Ohio, 1927-28.
Research Chemist, University of Cincinnati, 1928.
Graduate Assistant Instructor, Univ. of Cincinnati, 1928-32.
John Uri Lloyd Fellow at Univ. of Cincinnati, 1930-32.
Part time employment as Research Chemist by William S. Merrell Company of Cincinnati, 1929-30.
Employed by Kroger Food Foundation and Kroger Company in charge of Research and Development Department, 1932-38.
Employed by Food Machinery and Chemical Corporation, Lakeland, Florida, as Director of Research, 1938—

[fol. 40] That he made the study and analysis as shown on the two sheets attached hereto and which are made a part of this affidavit the same as if incorporated therein; and that it is a fair, scientific and correct analysis based upon scientific formulae and data as set forth therein.

That FD&C Red #32 is an oil soluble color used on the outside of oranges and does not penetrate the rag or inside of the orange; that such color has been used in the coloring of oranges since 1939, and to some extent prior thereto; and that more than 256,000,000 boxes had been shipped, colored with this color, at the time of the Food and Drug hearings, and that there was no instance of any detrimental effect to humans.

That the feeding tests used and shown in the testimony were unrealistic and in far greater proportions as to amount than would be ingested by human beings; that FD&C Red #32 is the only color certified for the coloring of oranges; that under any reasonable construction of the word "harmless" FD&C Red #32 is harmless; that the Food and Drug Administration has repeatedly said:

"There is, however, no evidence that, in the amounts used, and in the manner of use, in the coloring of citrus fruit, the product so colored is not safe for human consumption."

That the eating of oranges colored with said color would not be harmful in any way to human beings and that there is no danger to the public or the public health by reason [fol. 41-46] of the continuation of the use of such color.

(S.) R. D. Gerwe.

Sworn to and subscribed before me this 28 day of January, A. D. 1956.

(S.) Frank M. Vento, Notary Public, State of New York. (Seal.)

My commission expires: Mar. 30, 1957. No. 03-4094050.

Qualified in Bronx County. Certified in New York County.

Analysis of Dr. R. D. Gerwe, Research Dept., FM&CC, dated 3*16*54, Omitted hereinafter copied at page 112.

[fol. 47] UNITED STATES CIRCUIT COURT OF APPEALS FOR THE FIFTH CIRCUIT

No. 15948

FRANK R. SCHELL, Petitioner on Review

vs.

M. B. FOLSOM, Secretary of the Department of Health, Education and Welfare, Respondent on Review

PETITION FOR REVIEW—Filed February 8, 1956

J. Lewis Hall, P. O. Box 55, Tallahassee, Florida, Attorney for Petitioner.

[File endorsement omitted.]

[fol. 47a] To the Honorable Judges of the United States Circuit Court of Appeals for the Fifth Circuit:

Frank R. Schell, a citizen of the United States and of the State of Florida, whose place of business is at 1602.

Richardson Place, Tampa 6, Florida, presents this Petition for judicial review of an order entered by the Secretary of Health, Education and Welfare, dated November 10th, 1955, and, in support thereof, respectfully represents as follows:

I

The Nature of the Proceedings

Your Petitioner seeks a review of an order of the Secretary of Health, Education and Welfare, dated November 10th, 1955 (F.R. Doc. 55-9209, filed November 15, 1955) and published in the Federal Register under date of November 16, 1955, pp. 8492-8495, both inclusive, with the heading:

"Title 21—Food and Drugs

Chapter 1.—Food and Drug Administration, Department of Health, Education and Welfare:

Part 135—Color Certification Miscellaneous Amendment."

This order was entered by the said Secretary, statedly under the provisions of the Act of June 25, 1938, (c) 675, paragraph 406, 52 Stat. 1049; Reorg. Plan No. IV, par. 12, effective June 30, 1940; 5 F.R. 2422, 54 Stat. [fol. 47b] 1237, 21 U.S. Code Ann. Subparagraph 406 (b) of the Act of June 25, 1938, reads:

"The Secretary shall promulgate regulations providing for the listing of coal-tar colors which are harmless and suitable for use in food and for the certification of batches of such colors, with or without harmless diluents." (Title 21 USCA p. 209.)

The above mentioned order deleted the coal-tar food colors designated as FD&C Red No. 32 and FD&C Orange No. 2 from the list of certifiable colors and the action affecting the interests of this Petitioner appears in par. 5 of the conclusions.

Petitioner filed his exceptions and brief in opposition to said order, together with petition to re-open the proceedings and take additional testimony to rectify the omission of pertinent and important matters and things which latter petition was ignored by the said Secretary.

II

Jurisdiction of this Court

The Court has jurisdiction by virtue of the Federal Food, Drug and Cosmetic Act (Public Law 717—75th Congress, Chapter 675—3rd Session) Act of June 25, 1938, 52 Stat. 1055 and amendments thereto (21 U.S.C.A. 371) and the Administrative Procedure Act, Act of June 11, 1946, 60 Stat. 243 (Title 5 U.S.C.A. 1009).

[fol. 47c]

III

Facts and Statutes Upon Which Jurisdiction Is Based

(1) Your petitioner resides and has his place of business within the Fifth Circuit.

(2) An actual controversy exists as to the validity of the order hereinbefore and hereinafter referred to and Petitioner will be adversely affected by such order if placed in effect and is adversely affected and aggrieved by the action of such Agency entering the order and is entitled to have the order reviewed by Judicial review under the Statute referred to in Paragraph II.

(3) Your Petitioner originated and retains an interest in the several patents on what has become known as the Color Added process, being a process for artificially enhancing the varietal color of mature citrus fruits, particularly oranges, by the impregnation of the peel thereof with a certified food color. The food colors FD&C Orange No. 2 and FD&C Red. No. 32, attempted to be deleted by said order, are the only colors adapted or adaptable to such coloration of oranges at this time. Your Petitioner is also a producer of oranges, but derives his principal income from royalties from said Color Added process, which income would be destroyed by said order.

IV

Points Upon Which Petitioner Will Rely

Petitioner herewith presents the points upon which he [fol. 47d] will rely for reversal of the order of the Secretary, such points to be presented in the following order:

1. Nature of "Color Added" Process
2. Necessity for "Color Added"

3. The evidence upon which the order of the Secretary was entered is wholly insufficient
4. The order of the Secretary is unfounded in law.

(1) Nature of the Color Added Process

The Color Added process comprehends the use of a coloring medium comprising an oil-soluble certified food color (FD&C Orange No. 2 or FD&C Red No. 32, both attempted to be banned by the order of November 16, 1955, herein appealed from); a minute amount of solvent for the food colors; soap or another emulsifying and surface tension reducing agent, and water.

The oranges are immersed in this liquid for a period of two to three minutes, or the liquid is poured or sprayed on the oranges for a like period of time. The maximum temperature of the coloring medium is fixed by law at 123° F. The temperature of the inner juice is raised not over 2° F. by this process.

The color is absorbed from the coloring medium by the very thin layer of oily and waxy materials in the extreme outer surface of the peel, which layer is about 1/1000 of an inch thick. The color cannot penetrate beyond this outer layer of oily and waxy material and is chemically incapable of coloring the white cellulosic material of the peel, [fol. 47e] nor can it color the inner membranes (rag) or the juice cells or the juice of the orange.

The peel of an orange thus treated contains *four* parts of color per million parts of whole orange. The juice of an orange so colored contains *7/100 of one part of color per million parts of juice by weight*, that color being held in peel oil that escaped into the juice during extraction of said juice.

It should here be noted that while F&DA is contending for a right to prohibit the use of a color which, for 14 years, it has certified to be "harmless and suitable for use in foods" and which is used at the rate of 4 parts of color per million parts of the whole orange, and has no cumulative properties, F&DA has recently issued, under the provisions of Sub-Section 406 (a) of the 1938 FD&C Act, standards of tolerances for deleterious spray residues permitted to remain on citrus fruits and that these standards prescribe a tolerance of 7 p.p.m. for arsenate of lead, a known deadly

poison of known cumulative effect, being 175% of the peel content of the certified food color FD&C Red. No. 32 or FD&C Orange No. 2.

(2) Necessity for "Color Added"

All citrus producing areas harvest their early varieties while the peel is still green in color, although the fruit is mature by all standards. All areas use ethylene gas (1 cubic foot of gas to 3000 cubic feet of air) to decompose the green chlorophyll in the peel.

In the case of all varieties grown in Florida and Texas the orange thus degreened has a pale, sickly yellow appearance when the green color first disappears, and further [fol. 47f] exposure to the ethylene gas will deepen that color but little. The same is true of all California varieties *except* their Navel orange.

In the case of the California Navel orange, that variety, also, has a pale yellow coloration when the green first disappears, but further exposure to the ethylene gas, for another 24 to 36 hours, deepens that color to a rich, orange-red that is perfect in its eye appeal. A noted plant physiologist, after three years study of the subject, identified this added color as a species of harmless burn (comparable to a mild sunburn of the human skin) resulting from the action of the gas upon some unidentified constituent of the peel of the California Navel orange only.

Since the *natural* color of the California Navel, as disclosed when the green is first blanched out, is that pale, sickly yellow, then the color resulting from such further exposure to ethylene gas is obviously as artificial as that had from the use of "Color Added."

As was said by the Circuit Court of Appeals in Lexington Mill and Elevator Co. vs. U. S. (202 Fed 615; aff. U.S.S.C., 232 U.S. 399) where the issue was the propriety of bleaching the yellowish tint from flour:

> "The mixture referred to in the first subdivision must be held to include a chemical compound as well as a mechanical mixture. * * * *Similarly, the word 'colored' must be held to include any artificially produced change in the natural color of the substance.* * * * This is the evident intent of the statute." (Emphasis ours.)

This perfect artificial color gave to the California citrus [fol. 47g] industry a competitive advantage that was well nigh absolute, as is shown by the following figures:

For the shipping season of 1923-24, when the ethylene gas process first went into general use, Florida produced 13,150,000 boxes of oranges, Texas produced 6,000 boxes and California produced 24,153,000 boxes.

For the shipping season of 1934-35, Florida produced 15,600,000 boxes, Texas produced 650,000 boxes and California produced 45,047,000 boxes of oranges.

Florida, struggling against California's monopoly of a perfect artificial color, had increased her production, in eleven years, by only 2,450,000 boxes, and was having great difficulty in marketing even that small production. Texas shipped but little of her crop in interstate commerce. California, however, had increased her production by 20,894,000 boxes, or nearly nine times Florida's increase.

In the shipping season of 1934-35 the Color Added process went into use in Florida and Texas. Even with the handicap of being required to stamp each orange "Color Added," while the artificially colored California Navel carried no declaration of artificial color, the Color Added process largely equalized the monopoly of artificial color theretofore enjoyed by the California industry.

In 1944-45, just ten years later, Florida produced 42,800,000 boxes of oranges, an increase of 27,200,000 boxes; Texas produced 4,400,000 boxes, an increase of 3,750,000 boxes, and California in her best year ever, under very favorable growing conditions, produced 60,500,000 boxes (against 51,961,000 boxes in 1943-44 and 44,010,000 boxes in 1945-46) [fol. 47h] an increase over 1934-35 production of 15,453,000 boxes, largely due to increase in production capacity of older trees and of young trees planted before the impact of Color Added was fully evident.

Florida and Texas production continued to climb, until in 1951-52 Florida was producing 78,600,000 boxes; Texas which had increased to 5,200,000 boxes in 1947-48 before her two disastrous freezes in 1949-50 and 1950-51, was starting over with 300,000 boxes, while California was down to 38,410,000 boxes, a decrease of 22,090,000 boxes.

For the year 1954-55, Florida produced more than

90,000,000 boxes, while California's production was some 40,000,000 boxes.

There is no intent to claim that "Color Added" is due the entire credit for Florida's ability to market her present huge volume of oranges. On the contrary, when, in 1947-48, Florida's production reached 58,400,000 boxes, the peak production for which Color Added is entitled to a substantial part of the credit, we faced definite signs of overproduction. But in the meantime the frozen concentrated juice process was coming into full production and picked up the slack, enabling Florida to go on to new production heights.

From 1933 until 1938 F&DA, under the direction of Hon. Walter G. Campbell, Chief, who was fanatically opposed to the use of *any* artificial color on or in any food, beverage, drug or cosmetic, strove to outlaw the Color Added process. That opposition did not cease until [fol. 47i] the Congress by the FD&C Act of June 25, 1938, recognized the propriety of the Color Added process. In all such efforts Mr. Campbell had the vigorous assistance of a powerful ally, the California Citrus Growers Exchange.

If, as the result of F&DA's order of November 16th, 1955, the Color Added process was destroyed, as it would be, so that California's prior monopoly of artificial color was reinstated, the result would inevitably be chaos and ruin for the citrus industry of the United States.

Florida and Texas could not successfully market their present 30,000,000 boxes per annum of fresh fruit shipments, against California's competitive advantage of perfect artificial color. The Florida and Texas orange industry would become a canning operation, and the diversion of an additional 30,000,000 boxes into that channel would inevitably mean 50-cent oranges at the cannery platform.

The impact of the resulting tremendous volumes of cheap frozen concentrated juice on retail markets would break the price of California oranges to a point where their growers would be driven from production, and low prices for oranges at canneries would have the same effect upon Florida and Texas growers.

In short, the Color Added process is, today, one of the indispensable stabilizing factors upon which the citrus industry of the United States is dependent, not alone for continued prosperity but for its existence as an industry.

Yet F&DA would destroy that process, and seriously [fol. 47j] injure a basic agricultural industry of two States, with consequent grave consequences to the entire economy of those States, in order to enforce an arbitrary and capricious interpretation of that one word "harmless."

(3) The Evidence Upon Which the Order of the Secretary Was Entered Is Wholly Insufficient

FD&C Orange No. 2, which had been in use for some years, was re-certified under the new law in 1939.

FD&C Red No. 32 underwent exhaustive tests by eminent private toxicologists whose reports were filed with the application for certification of that color. Based thereon, temporary certification was granted by F&DA, whose toxicologists then ran certain drastic tests designed to check the private reports, and permanent certification was granted in 1939.

F&DA, however, instituted other tests that ran for five to six years (1938-1944) as a check against possible cumulative toxicity, and the results showed no such cumulative toxicity.

In late 1952, other short term tests were run for the obviously predetermined purpose of supporting the claim now made by F&DA that the color cannot be termed "harmless" because they could make test animals ill by feeding them excessive quantities of the color.

Any extended discussion of these "short-dog" 1952-53 tests is made unnecessary by the admission in the order of November 10th that the color is harmless when consumed in normal and usual amounts but there is evidence of toxicity when fed in larger amounts, i.e., an animal [fol. 47k] can be made ill if forced to consume excessive amounts.

Nevertheless we add here a short analysis of the experiments and results thereof relied upon by F&DA to support the order of the Secretary.

In Dr. Vos' testimony, shown as Exhibit No. 4 in the Hearing held January 19, 1954, a series of experimental feeding tests were reported.

On page 1, results are recorded covering an experiment conducted in 1940 in which rats were fed a daily diet containing 0.10% FD&C Red No. 32 over an extended

period of time beginning with rats which were only 21-22 days old.

On a comparable basis, assuming that a man eats an average of 4 pounds of food per day, 0.1% Red No. 32 would amount to 0.004 lbs. of color or 1.8 grams. One pound is equivalent to 453.6 grams. In order to eat 1.8 grams of color (on the basis of 0.0008 grams of color per orange) a man would have to eat 2250 oranges—peel and all—each day. This is approximately 1100 pounds of oranges that would have to be eaten per day and is approximately 7 times a man's weight.

Another comparison might be made by assuming that a man ate 6 oranges, peel and all, per day. On the basis that a color added orange contains 0.0008 grams of color, this would amount to 0.0048 grams. By comparison with the rat feeding level of 0.1% in the diet, and a man eating 4 lbs. of food per day he would have to eat 1.812 grams of [fol. 471] dye. $1.812 \div 0.0048 = 378$. Thus the rats were fed at a level of 378 times as much color as a man would get if he ate 6 oranges, peel inclusive, per day. This would amount to 1134 times as much, on the basis that a man ate two oranges per day.

On page 4 of the Exhibit is reported an experiment in which rats were fed at 2.0; 1.0; 0.5 and 0.25% levels. Since at the 0.1% level a man would have to eat 2250 oranges, then at these levels he would have to eat 45,000; 22,500; 11,250; and 5,625 oranges per day, respectively.

Assuming on the other hand that a man ate 6 oranges, peel included, per day, then on the basis of 0.0008 grams of color per orange, the total would be 0.0048 grams. On the basis of a man eating 4 lbs. of food per day, the 2.0% level would require 36.24 grams of dye. This amounts to $36.24 \div 0.0048$ or 7550. Thus the rats were fed at the rate of 7550 times as much color as a man could get if he ate 6 oranges (peel inclusive) per day. At the 0.25% level this rate is 944.

In the 1938-44 experiments reported on page 21, dogs were fed by means of capsules as much as 100 mgs. of color per kilogram of body weight per day. An average man weighs 70 kilograms (150 lbs.) and therefore would consume 7000 mgs. of color if fed at the same rate. Since a color added orange contains 0.8 mg. of color it would take 8750 oranges for a man to get 7000 mgs. of color per day. This

is approximately 4380 pounds or about 29 times as much as the man weighs.

Again assuming that a man might eat 6 oranges (4.8 mg. of color) per day then this represents that the dogs were [47m] fed at a level of 7000/4.8 or 1458 times as great. Yet in this report in spite of the high level of feeding, it was reported that the dogs showed no ill effects except for moderate weight loss.

Subsequent to this, the same dogs were fed at the rate of 20 mg. per kilogram per day for a period of 5 years with no ill effects. This is ⅕ of the 100 mg. level. On a comparable basis a man would have to eat 1750 oranges per day for the five year period. In this experiment the dogs were found to experience no ill effects.

In the 1952 experiment reported on page 29, dogs were fasted over night, then given 200 mg. of color in a capsule, and then fed two hours later. It was reported that 8 of 10 dogs developed diarrhea. This, of course, is an unnatural way of feeding. Nevertheless, on this basis a man would have to eat 7 times that amount of color, or 1400 mg. on a comparable basis and this would require 1750 oranges. This amounts to 875 pounds or more than 5 times the man's own weight. On the basis of 6 oranges per day the dogs were fed at a level of 292 times as much as a man would get if he ate 6 oranges (peel inclusive) per day.

Dr. L. G. MacDowell, Director of Research for Florida Citrus Commission, testified that his laboratory's analysis of juice extracted commercially from color-added oranges showed that it contained 0.07 parts per million of Red No. 32. It should be pointed out that rarely, if ever, does a canning plant run 100% colored oranges. Generally the fruit is a mixture of grove-run and packing house elimination. It is true also that this trace of color gets into the [47n] juice in the course of the commercial extraction and is not in the juice prior to that operation.

It may be assumed that an individual might drink as much as 8 ozs. (approximately 250 grams) of juice per day. This represents only 0.0175 mg. or 0.0000175 grams (453.6 grams per pound) of color. Assuming that a man eats 4 lbs. (1800 grams) of total food per day this amount of color is 0.000001% of the total daily diet. Compared with those

experiments in which Dr. Vos employed feeding levels of 0.1%, this represents 1/100,000 of his level or it might be said that his level was 100,000 times as much as a man might get by drinking 8 ozs. of orange juice per day.

As stated earlier, Dr. Vos reported on page 21 and 22 of Exhibit #4 that in experiments conducted in 1938-1944 dogs were fed 20 mg. of color per kilogram of body weight per day over a period of five years and no adverse effects were noted nor was there any accumulative effect.

On a comparable basis a man weighing 70 kilograms would have to eat 70×20 or 1400 mg. of dye per day. As shown above, 8 oz. of orange juice might possibly contain as much as 0.0175 mg. of dye. This then would represent $(1400 \div 0.0175)$ or about 80,000 such 8 oz. drinks or 5000 gallons of juice per day. By analogy a person could drink a 5000 gallon tank full of orange juice every day without suffering any ill effects attributable to the presence of dyestuff.

On the basis of a man drinking 8 ozs. of juice per day containing 0.0175 mg. of color, this is only 1/80,000 of the [fol. 47o] intake which caused "no effect" when the dogs were thus fed for five years.

In view of the foregoing considerations, it is submitted that the feeding levels of this dye employed in the experiments reported by Dr. Vos are fantastically greater than the amounts or levels that a person might get by eating oranges or by drinking the juice. It is clearly evident from the testimony presented at the Hearing that no evidence was submitted to show that consumption of the infinitesimal amounts of dye which might be consumed by eating color-added oranges or juice therefrom has any harmful effects whatsoever.

(4) The Order of the Secretary Is Unfounded in Law

The principal issue in these proceedings is the legality or illegality of the interpretation and construction which F&DA is attempting to place upon the word "harmless" as used in Sub-Section (b) of Section 406 of the 1938 Food, Drug and Cosmetic Act.

The order of the Secretary is based upon the theory that for a substance to be "harmless" it must have "zero

toxicity" or in other words must be completely "harmless" and utterly devoid of capability to cause any ill effect whatsoever without regard to the amount or quantity that must be ingested to cause such ill effects, which theory is contrary to law and reason and is repugnant to and violative of the fundamental rule of construction that all words and language in a statute must be given a reasonable interpretation and shall not be construed or inter- [fol. 47p] preted in such manner as to produce an absurd result or defeat the plain and clear legislative intent.

In short, F&DA contends that since the word "harmless" is not modified by other language in that sub-section, it can only be construed to mean that if F&DA can make any living creature ill by feeding to that creature fantastic amounts of a certified food color, under fantastic conditions of usage, then that certified food color is not "harmless" within the meaning of the statute and may not be certified as "harmless and suitable for use" on or in foods.

The attempted construction of the word "harmless" is unlawful (and constitutes an attempt to arrogate to F&DA, by usurpation and indirection, powers which the Congress has repeatedly refused to grant to F&DA) in that:

(a) F&DA's construction of the word "harmless" is contrary to the settled rule of construction for determining the will and intent of the Congress.

(b) It is contrary to the settled rule of law that the Congress will not be presumed to have enacted or prescribed an impossible or absurd thing, i.e. (in this case) set up an impossible test as a condition precedent to an instructed action.

(c) It is contrary to the settled rule of law that the construction placed upon the language of a statute must be a "reasonable" construction.

(d) It is contrary to the settled rule of law that long [fol. 47q] continued construction of a statute by the agency charged with enforcement thereof may not be disturbed save for weighty and cogent reasons.

(e) The construction attempted by F&DA is contrary to the public interest.

These points will be discussed in that order.

(a) F&DA's construction of the word "harmless" is contrary to the settled rule of construction for determining the will and intent of the Congress.

It has long been a settled rule of construction that when the Congress uses a word or term that has theretofore been authoritatively construed, as to like use, by a Court of competent jurisdiction, it must be assumed that the Congress was familiar with such interpretation and construction and used that word or term in the same sense.

In the case of the word "harmless" as used in the Federal Food and Drug Act, the Supreme Court of the United States has construed that word to mean, in effect, that it is *harmless when consumed in the amounts and under the conditions of usual or customary usage.*

(b) It is contrary to the settled rule of law that the Congress will not be presumed to have enacted or prescribed an impossible thing, i.e., (in this case) set up an impossible test as a condition precedent to an instructed action.

F&DA's contention that the Congress prescribed "zero toxicity" when it used the word "harmless" in Sub-Section [fol. 47r] 406 (b) of the statute, does violence to the mentioned rule.

It is a well known fact of medical science that every living creature has a limit of tolerance for every substance ingested, whether that substance be an article of food, or liquid, or a food color, or a drug, or some other chemical. If *any* substance be consumed, voluntarily or involuntarily, in amounts in excess of that creature's tolerance therefor, then that creature will develop an allergy for that substance, or will otherwise be made ill by such overfeeding, even if that substance be an indispensable liquid or article of food, such as pure water or pure protein, which are the substances of life itself.

The first and usual reaction to such overfeeding of any substance is vomiting or diarrhea (suffered by dogs so overfed in F&DA tests) which are Nature's methods of ridding the body of toxic matter, or of other substances which, in themselves, are completely harmless, even bene-

ficial, but which, by such overfeeding, have become nauseating or injurious to that person or animal. Such illness, thus induced, does not even remotely imply that the substance so abused is in anywise injurious to human health when used in any imaginable amounts or under any imaginable conditions of ordinary and customary usage. F&DA are not unaware of this simple fact of medical science, hence are also advised that the results of tests employing such massive doses of these food colors are completely meaningless, insofar as concerns any possibility whatever of injury to human health.

> (c) It is contrary to the settled rule of law that the [fol. 47s] construction placed upon the language of a statute must be a "reasonable" construction.

We think it is clear from the foregoing that F&DA are attempting to place upon the word "harmless" as used in Sub-Section 406(b) of this statute a construction that is not only unreasonable but is definitely repugnant to sound reason, since there is no article of food, drink, drug or color that can meet a standard of "zero toxicity" when fed in excessive amounts under abnormal conditions.

> (d) It is contrary to the settled rule of law that long continued construction of a statute by the agency charged with enforcement thereof may not be disturbed save for weighty and cogent reasons.

The construction of the word "harmless" for which we contend is that construction which was administratively applied thereto in 1938 by Honorable Walter G. Campbell, Chief of the F&DA, immediately following the enactment of the 1938 FD&C Act, of which he was not only the principal author and mover for its enactment, but was also the administrative officer charged with the initial enforcement thereof.

Not until 14 years after the enactment of that Food and Drug Bill, did we hear so much as a suggestion that these colors, or any product colored therewith, could ever present any danger to human health, and we heard it then only after certain persons from the California citrus industry recommended the use of the Color Added process in that State, contrary to the wishes of the old allies of F&DA.

[47t] On this point, the United States Supreme Court has this to say:

> *"It is the settled rule that the practical interpretation of an ambiguous or doubtful statute that has been acted upon by officials charged with its administration will not be disturbed except for weighty reasons."* (Brewster v. Gage, 280 U.S. 327.) (Emphasis ours.)
>
> "Conceding that the proper classification of the railway is not free from difficulty, *all doubt is removed* by the application of *the settled rule that administrative construction* is entitled to great weight and *should not be overturned except for cogent reasons."* (U. S. v. CNS&M R.R. Co., 288 U.S. 1.) (Emphasis ours.)

As against the "settled rule" that there must be weighty and cogent reasons for upsetting the construction placed on the word "harmless" by Mr. Campbell, who wrote the Act, F&DA have advanced no reason of any kind or character for upsetting such construction except that the present Commissioner does not agree with the construction placed thereon by each of his three predecessors.

All that they can say, all that they have said, in support of the position they have taken in the instant case is that they can make a dog sick with this color if they feed enough of it to the dog, hence the color is not "harmless." They admit, as disclosed by the record, that they have not even attempted to relate the results of their alleged experimental work with any possible danger to human health; that their contention that the dye is not "harmless" is based solely [47u] upon the results of the feeding tests before mentioned. They admit that knowledge of the amount of dosage and conditions of use are necessary to a determination of toxicity or possible danger to human health, then admit, further, that they have no idea how much of this color would have to be consumed by a human being in order to adversely affect the health of that person.

(e) The construction attempted by F&DA is contrary to the public interest.

F&DA is attempting, by administrative action, to establish a new and vicious concept of law, i.e., that if any

product used as, or in, or on an article of food can, by abuse thereof, by made harmful to animal or human health, the manufacture and sale thereof in interstate commerce may be prohibited by F&DA. The food, beverage, drug and cosmetic industries would then exist only at the pleasure of whomever was appointed Commissioner of Food and Drug Administration.

Prayer for Relief

Wherefore, Petitioner hereinbefore named has caused this Petition to be signed in his behalf by his undersigned attorney and petitioner respectfully prays that this Honorable Court grant a review of the proceedings resulting in the order of the Secretary of Health, Education, and Welfare, dated November 10, 1955 as hereinbefore referred to and the order itself; that a copy of this Petition and the Petition for Stay be transmitted to the Secretary of Health, Education and Welfare of the United States; and that the Secretary be required to certify and file with this Court a transcript of the record upon which the said order was entered as required by law; and that upon [fols. 47v-51] such review the above described order be set aside insofar as it relates to FD&C Red #32 and FD&C Orange #2 and held for naught; that this Court enter an order setting aside temporarily and staying the taking effect of the order of the Secretary of Health, Education and Welfare insofar as it relates to the use of FD&C Red #32 and FD&C Orange #2 until the final determination of the petition for review in this case; that this Honorable Court enter a stay order, injunction or any and all necessary and appropriate process to postpone the effective date of the Sectretary's order insofar as it relates to FD&C Red #32 and FD&C Orange #2 and to preserve status or rights of this petitioner pending conclusion of the review proceedings, or if the Court in its discretion, should determine that the relief prayed for hereinbefore should not apply to the entire order insofar as it affects FD&C Red #32 and FD&C Orange #2, then petitioner prays that the Honorable Court grant a stay order or other orders staying the operation of the Secretary's order insofar as it relates to the use of FD&C Red #32 and FD&C Orange #2 for the coloring of ma-

ture oranges, when harmless in the manner and quantity as used; and that Petitioner may have such other and further relief as the allegations herein may warrant and as to the Court may seem meet and proper.

Dated February 6, 1946

(S.) J. Lewis Hall, P. O. Box 55, Tallahassee, Florida, Attorney for Petitioner.

[fol. 52] Saturday, December 19, 1953.

BEFORE DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Part 135]

[Docket No. FDC-60]

Color Certification

NOTICE OF HEARING TO AMEND REGULATIONS

In the matter of amending §§ 135.3 and 135.11 of the color certification regulations:

Upon the initiative of the Secretary of Health, Education, and Welfare and in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (secs. 406 (b), 504, 604, 701, 52 Stat. 1049, 1052, 1055; 21 U.S.C. 346 (b), 354, 364, 371; 67 Stat. 18), notice is hereby given that a public hearing will be held commencing at 10 o'clock in the morning of January 19, 1954, in Room G-747A, Health, Education, and Welfare Building, 330 Independence Avenue SW., Washington, D. C., for the purpose of receiving evidence upon the basis of which to amend the regulations for the certification of coal-tar colors (21 CFR Part 135, as amended 21 CFR, 1952 Supp.) in the following respects:

1. It is proposed to amend § 135.3 *List of straight colors and specifications for their certification for use in foods, drugs, and cosmetics* by deleting the names of the following straight colors and the respective specifications therefor:

FD&C Red No. 32.
FD&C Orange No. 1.
FD&C Orange No. 2.

2. It is propsed to amend § 135.11(d)(2) to read as follows:

§ 135.11 *Labeling.* • • •

(d) No batch of a mixture shall be certified under this part if:

(2) The name of such mixture is the same as or simulates the name of a previously certified batch of a mixture containing a different substance, or a different precentage of a pure dye; but this provision shall not apply if:

(i) The person who requests certification of such batch is the owner of such name and has given 3 months' written notice to the Food and Drug Administration specifying the change to be made in the composition of such mixture; or

(ii) Such change results from removal of a color from the listings in §§ 135.3, 135.4, or § 135.5.

At the hearing, evidence will be restricted to testimony and exhibits relevant and material to these proposals. The hearing will be conducted in accordance with the rules of practice provided therefor. Mr. Leonard D. Hardy is hereby designated as presiding officer to conduct the hearing in the place of the Secretary, with full authority to administer oaths and affirmations and to do all other things appropriate to the conduct of the hearing. The presiding officer is required to certify the entire record of the proceedings to the Secretary for initial decision. The proposed amendment for consideration at the hearing is subject to adoption, rejection, or modification by the Secretary as the evidence adduced at the hearing may require.

Dated: December 15, 1953.

Oveta Culp Hobby, Secretary. (Seal.)

[F. R. Doc. 53-10563; Filed, Dec. 18, 1953; 8:51 a. m.]

[fol. 53] Thursday December 30, 1954.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Part 135]

[Docket No. FDC—60]

Color Certification

NOTICE OF PROPOSED RULE MAKING

In the matter of amending §§ 135.3, 135.5, and 135.11 of the color-certification regulations:

It is proposed that, by virtue of the authority vested in the Secretary of Health, Education, and Welfare by the Federal Food, Drug and Cosmetic Act (secs. 406 (b), 504, 604, 701; 52 Stat 1049, 1052, 1055; 21 U. S. C. 346 (b) 354, 364, 371; 67 Stat. 18), and upon the basis of substantial evidence received at the public hearing held pursuant to the notice published in the FEDERAL REGISTER on December 19, 1953 (18 F. R. 8600), and upon consideration of the briefs filed thereafter, the following order be made:

Findings of fact.[1] 1. After a hearing held beginning February 6, 1939, concerning regulations for certification of coal-tars colors, the coal-tar color now listed as FD&C Orange No. 1 (monosodium salt of 4-*p*-sulfophenylazo-1-naphthol) and the coal-tar color now listed as FD&C Orange No. 2 (1-*o*-tolylazo-2-naphthol) were found to be harmless and suitable for use in food, drugs, and cosmetics. After a hearing held beginning on July 5, 1939, concerning amendment of the coal-tar regulations, the coal-tar color now listed as FD&C Red No. 32 (1-xylylazo-2-naphthol) was found to be harmless and suitable for use in food, drugs, and cosmetics. In accordance with these findings, these three colors, among others, were listed with appropriate

[1] The citations following each finding of fact refer to the pages of the transcript of the testimony and the exhibits received in evidence at the hearing, except for citations to the FEDERAL REGISTER, where applicable.

specifications of identity and quality in the coal-tar color regulations (21 CFR 135.3) as certifiable for use in food, drugs, and cosmetics. (4 F. R. 1922, 1926, 1937, 3931, 3936, 3937; R. 46)

2. Because of advances in knowledge and techniques in the field of pharmacology, the Food and Drug Administration has initiated new tests to explore more fully the toxicity of the certifiable coal-tar colors. This involves the application of all techniques and procedures now considered necessary to assure proper evaluation. A number of these tests, with present-day techniques and procedures, have been conducted by the Division of Pharmacology of the Food and Drug Administration, using FD&C Orange No. 1, FD&C Orange No. 2, and FD&C Red No. 32.

Tests that have been terminated are:

a. FD&C Orange No. 1:

i. Chronic feeding tests in rats with diets containing 0.1, 0.5, 1, and 2 percent.

ii. Chronic oral administration to dogs at doses of 5 milligrams per kilogram of body weight and 100 milligrams per kilogram of body weight.

iii. Cathartic tests in dogs, using single oral dose.

b. FD&C Orange No. 2:

i. Chronic feeding tests in rats with diets containing 0.01, 0.05, 0.1, 0.2, and 0.25 percent.

ii. Tests designed to determine carcinogenicity in rats, using weekly subcutaneous injections of 0.1 milliliter of a 5-percent suspension. (The test was discontinued after 8 injections, because of toxicity.)

iii. Carcinogenicity tests in mice, using subcutaneous implantation of 12.1 milligrams at intervals for 30 to 55 weeks.

iv. Chronic oral administration to dogs at doses of 5, 20, and 100 milligrams per kilogram of body weight per day.

v. Chronic feeding tests in dogs at dietary levels of 0.2 percent and 0.04 percent.

vi. Cathartic tests in dogs, using single oral dose.

c. FD&C Red No. 32:

i. Chronic feeding tests in rats, with diets containing 0.1 percent.

ii. Subacute feeding tests in rats, with diets containing 0.25, 0.5, 1, and 2 percent.

iii. Chronic feeding tests in rats, with diets containing 0.1 percent and 0.25 percent.

iv. Carcinogenicity tests in rats, using weekly subcutaneous injections of 0.1 cubic centimeter to 0.2 cubic centimeter of a 5-percent suspension. (A second experiment using weekly subcutaneous injections of 0.1 cubic centimeter of a 1-percent suspension, was discontinued after 8 injections, because of toxicity observed in rats receiving FD&C Orange No. 2 in another part of this experiment.)

v. Carcinogenicity tests in mice, using subcutaneous implanation of 10.8 milligrams at intervals for 35 weeks to 47 weeks.

vi. Chronic oral administration to dogs at doses of 5, 20, and 100 milligrams per kilogram of body weight per day.

vii. Chronic feeding tests in dogs at dietary levels of 0.04 percent and 0.2 percent.

viii. Cathartic tests in dogs, using single oral dose.

Tests that were still in progress at the time of the hearing were:

a. FD&C Orange No. 1:

i. Carcinogenicity tests in rats, using weekly subcutaneous injections of from 0.25 milliliter to 1.0 milliliter doses of a 2-percent solution.

ii. Chronic feeding tests in dogs at dietary levels of 0.2 percent and 1 percent.

b. FD&C Red No. 32:

i. Chronic feeding tests in dogs at a dietary level of 0.01 percent.

Tests of the three colors by external application to determine whether they are toxic when applied externally were being set up at the time of the hearing. (R. 8-78; Ex. 2, 3, 4)

3. The tests that have been concluded are tests normally employed to determine the toxicity of substances taken internally by man. The results of these investigations show that each of the coal-tar colors FD&C Orange No. 1, FD&C Orange No. 2, and FD&C Red No. 32, taken internally,

caused marked damage to various vital organs of the test animals, significant changes in body weight, and premature death.

FD&C Orange No. 1 caused the premature death of all rats on a diet containing 2.0 percent of the test substance. In rats on a diet containing 1.0 percent of this substance there were marked retardation of growth, increased mortality, and chronic congestion and enlargement of the spleen. These same manifestations, to a somewhat lesser extent, were encountered in rats consuming a diet containing 0.5 percent of FD&C Orange No. 1. Dogs consuming 100 milligrams per kilogram per day of FD&C Orange No. 1 died in 26 months to 33 months. They had occasional diarrhea while alive and manifested terminal weight loss. Autopsy revealed congestion and atrophy of the liver attributable to the test substance. On a diet containing 1.0 percent of FD&C Orange No. 1, dogs exhibited chronic diarrhea, rapid deterioration, and weight loss. Autopsy revealed muscular dystrophy and testicular and prostatic atrophy. These same manifestations occurred to a lesser extent in dogs on a diet containing 0.2 percent of FD&C Orange No. 1. A single dose of 100 milligrams to 200 milligrams of FD&C Orange No. 1 produced diarrhea in most dogs. Human volunteers taking 80 milligrams to 100 milligrams in a single dose experienced marked griping and diarrhea.

FD&C Orange No. 2 caused severe growth retardation and increased mortality to rats on a diet containing 0.25 percent of the test substance. At 0.2 percent of the rats' diet there were increased mortality and degeneration of the liver. At a level of 0.1 percent of the substance in the diet, the rats exhibited marked growth retardation. At a level of 0.5 percent, autopsy revealed enlargement of the right side of the heart and slight hypertrophy or hyperplasia of the cells in the liver. Five milligrams per week given to rats by subcutaneous injection caused increased mortality and moderate growth retardation. Dogs consuming 100 milligrams per kilogram of body weight per day of FD&C Orange No. 2 lost weight or gained poorly. Twenty milligrams per kilogram of body weight per day caused one dog in the experiment to gain weight poorly. Dogs on a diet containing 0.2 percent of the test substance had diarrhea at

the beginning of the experiment and exhibited rapid deterioration and weight loss. Autopsy revealed atrophy of various vital organs caused by the color. At 0.04 percent of the diet, dogs gradually deteriorated and lost weight, and autopsy revealed atrophy of various vital organs. A single dose of 200 milligrams produced diarrhea in dogs.

When FD&C Red. No. 32 was fed to rats at a level of 2.0 percent of the diet, all the rats died within a week. At a 1.0-percent level, death occurred within 12 days. At 0.5 percent most of the rats died within 26 days. At 0.25 percent approximately half of the rats died within 3 months. All the rats showed marked growth retardation and anemia. Autopsy revealed moderate to marked liver damage. Sim- [fols. 54-56] ilar but less severe results were obtained with rats on a diet containing 0.1 percent of FD&C Red No. 32. In addition to liver damage, however, autopsy also revealed enlargement of the right side of the heart in this latter group. Subcutaneous injection of approximately 10 milligrams per week caused death within 8 weeks to most rats on the experiment. These rats exhibited anemia, hemorrhage, and reduction in the size of the liver. Dogs taking 100 milligrams per kilogram of body weight per day showed moderate weight loss. A level of 0.2 percent of FD&C Red No. 32 in the diet of dogs caused rapid deterioration and weight loss and sporadic diarrhea; 0.04 percent caused gradual deterioration and weight loss, sporadic diarrhea, moderate atrophy of vital organs, and muscular dystrophy; 0.01 percent in the diet caused weight loss and the death of one out of four dogs. A single oral dose of 100 milligrams or 200 milligrams gave diarrhea in the majority of the dogs tested.

The results of pharmacological tests, conducted by qualified investigators using recognized scientific methods, establish that the colors are not harmless substances, but on the contrary are definitely toxic and exert pronounced physiological effects on body tissue. The experimental work on man is limited, and except for Orange 1, adverse effects on man have not been definitely confirmed. (R. 8-87, Ex. 2, 3, 4)

4. The coal-tar colors listed in the regulations as FD&C Orange No. 1, FD&C Orange No. 2, and FD&C Red No. 32 may be used at present in externally applied drugs and cosmetics as well as products for internal consumption. Tests

designed to examine the toxicity of these colors, when used externally, are not complete. (R. 46-48, 63-65)

5. Modification of 21 CFR 135.11(d)(2) to eliminate the requirement for 3 months' written notice of change in composition of a coal-tar color mixture will facilitate the marketing of substitute mixtures and reduce confusion that may result from the deletion of a straight color from the listings at 21 CFR 135.3, 135.4, and 135.5. (R. 88, 89)

Conclusions. 1. Based upon the evidence of toxicity presented at the hearing, the coal-tar colors FD&C Orange No. 1 (monosodium salt of 4-*p*-sulfophenylazo-1-naphthol), FD&C Orange No. 2 (1-*o*-tolylazo-2-naphthol), and FD&C Red No. 32 (1-xylylazo-2-naphthol), described in the coal-tar color regulations, 21 CFR 135.3, are not harmless and suitable for use within the meaning of sections 406(b), 504, and 604 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346(b), 354, and 364) in coloring food or for use in coloring drugs or cosmetics intended for other than external application.

2. The coal-tar colors FD&C Orange No. 1, FD&C Orange No. 2, and FD&C Red No. 32 should be deleted from the listing at 21 CFR 135.3, since the Secretary cannot continue to list these colors as colors that the Food and Drug Administration will certify as harmless and suitable for use in coloring food or in coloring drugs and cosmetics intended for other than external application.

3. Colors conforming to the present regulations and specifications for FD&C Orange No. 1, FD&C Orange No. 2, and FD&C Red No. 32 should be added to the listing at 21 CFR 135.5, for use in coloring externally applied drugs and cosmetics only.

4. The provisions of 21 CFR 135.11(d)(2) requiring 3 months' written notice of a change in the composition of a coal-tar color mixture should be waived when such change is made necessary by deletion of one or more straight colors from the listing at 21 CFR 135.3, 135.4, or 135.5.

Therefore, it is proposed that Part 135—Color Certification be amended in the following respects:

1. In § 135.3 (a), delete the colors FD&C Orange No. 1, FD&C Orange No. 2, and FD&C Red No. 32.

2. Add the following to § 135.5 (a):

Ext D&C Orange No. 3

Specifications

Monosodium salt of 4-*p*-sulfophenylazo-1-naphthol.
Volatile matter (at 135° C.), not more than 10.0 percent.
Water-insoluble matter, not more than 0.3 percent.
Ether extracts, not more than 0.2 percent.
a-Naphthol, not more than 0.1 percent.
Chlorides and sulfates of sodium, not more than 4.0 percent.
Mixed oxides, not more than 1.0 percent.
Orange II, not more than 5.0 percent.
Pure dye (as determined by titration with titanium trichloride), not less than 85.0 percent.

Ext D&C Orange No. 4

Specifications

1-*o*-Tolylazo-2-naphthol.
Volatile matter (at 100° C.), not more than 0.5 percent.
Sulfated ash, not more than 0.3 percent.
Water-soluble matter, not more than 0.3 percent.
Matter insoluable in carbon tetrachloride, not more than 0.5 percent.
o-Toluidine, not more than 0.05 percent.
β-Naphthol, not more than 0.05 percent.
Pure dye (as determined by titration with titanium trichloride), not less than 98.0 percent.
Melting point, not less than 128.0° C.

Ext D&C Red No. 14

Specifications

1-Xylylazo-2-naphthol.
Volatile matter (at 100° C.), not more than 0.5 percent.
Sulfated ash, not more than 0.3 percent.
Water-soluble matter, not more than 0.3 percent.
Matter insoluable in carbon tetrachloride, not more than 0.5 percent.
Xylidene, not more than 0.1 percent.
β-Naphthol, not more than 0.05 percent.

m-Xylidine in xylidine obtained by reduction of the dye, not more than 30.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 97.0 percent.

Boiling range of xylidine, obtained by reduction of the dye, 95 percent between 212°-232° C.

3. Amend § 135.11(d)(2) so that, as amended, it will read as follows:

§ 135.11 *Labeling.* • • •

(d) • • •

(2) The name of such mixture is the same as or simulates the name of a previolusly certified batch of a mixture containing a different substance, or a different percentage of a pure dye; but this provision shall not apply if:

(i) The person who requests certification of such batch is the owner of such name and has given 3 months' written notice to the Food and Drug Administration specifying the change to be made in the composition of such mixture; or

(ii) Such change results from removal of a color from the listings in §§ 135.3, 135.4, and 135.5.

Any interested person whose appearance was filed at the hearing may, within 30 days from the date of the publication of this tentative order in the FEDERAL REGISTER, file with the Hearing Clerk, Department of Health, Education, and Welfare, Room 5440, Health, Education, and Welfare Building, 330 Independence Avenue SW., Washington, D. C., written exceptions thereto. Exceptions shall point out with particularity the alleged errors in this tentative order and shall contain specific references to the pages of the transcript of the testimony or to the exhibits on which such exceptions are based. Such exceptions may be accompanied by a memorandum or brief in support thereof. Exceptions and accompanying memoranda or briefs shall be submitted in quintuplicate.

Dated: December 22, 1954.

Nelson A. Rockefeller, Acting Secretary. (Seal.)

[F. R. Doc. 54-10346; Filed, Dec. 29, 1954; 8:49 a. m.]

[fol. 57] **Before the Secretary of Health, Education, and Welfare.**

In the Matter of: Amending Sections 135.3 and 135.11 of the Color Certification Regulations of the Department of Health, Education, and Welfare.

(21 CFR, Part 135)

(Docket No. FDC-60)

Brief of Chase & Company and Randall Chase.

Statement

On January 19, 1954, pursuant to notice of hearing of [fol. 58] proposed rule making, a hearing was held before Leonard D. Hardy, Presiding Officer, acting on behalf of the Secretary of Health, Education, and Welfare. The hearing dealt, in part, with the proposal of the Secretary to amend Section 135.3 of the color certification regulations by deleting the names of FD&C Orange No. 1, FD&C Orange No. 2, and FD&C Red No. 32 and the respective specifications therefor. Chase & Company which raises oranges in the State of Florida and ships them in interstate commerce, entered an appearance and participated in the hearing.

The primary purpose of the hearing was receive evidence for the purpose of determining whether to amend the reguations for the certification of coal-tar colors by deleting from Section 135.3 the dyes specified above because of data which had been obtained by the Food and Drug Administration indicating that the substances were not harmless, as required by Section 406(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 346(b). On December 22, 1954, a notice of proposed rule making was issued by the Acting Secretary. Based upon the findings of fact set forth in the notice, the Acting Secretary concluded in part that the three dyes are not harmless and suitable for use in coloring food and may not continue to be listed and certified for that purpose.

The notice of proposed rule making states that any interested person whose appearance was noted at the hearing may file written exceptions to the tentative order. Chase

& Company, and Randall Chase, on behalf of the company and on his own behalf as a consumer, believe that an extremely important problem is presented from the viewpoint [fol. 59] of those growers of oranges who do not wish to perpetrate a fraud upon the consumer, and that the problem directly concerns the public health and purse. In view of these considerations, we seek here to establish:

(1) The findings and conclusions of the Acting Secretary that the colors involved are not harmless are supported by Substantial and uncontradicted evidence in the record.

Allowed.

(2) The findings and proposed order are defective in not dealing with the problem of whether the dyes, particularly when employed on oranges, do not render the food adulterated and misbranded under the Federal Food, Drug, and Cosmetic Act and thus can be said to be "suitable for use" under Section 406(b) of the statute.

Denied.

(3) Exception is and must be taken to those portions of the order, "2" and "3" of the proposed amendments to Part 135—Color Certification, purporting to permit various colors to be utilized in foods, since no fiinding has been made that the dyes, when used in or on food, do not adulterate or misbrand the food in violation of the Act and thus can be said to be "suitable for use."

Denied.

[fol. 60] Argument

I

The proposed order and findings of fact with respect to "harmlessness" are based on, and supported by, substantial evidence of record at the hearing.

By reason of advances in the vital field of pharmacology and the results of experimental work in this country and other countries which created serious doubts as to the chronic toxicity and carcinogenicity of the certified coal-tar colors, the Food and Drug Administration initiated labo-

ratory and experimental work to evaluate the long-range hazards created by the use of these dyes. It may be added, parenthetically, that such a burden was not intended to be placed, and should not have been placed, upon the Food and Drug Administration, with its extremely limited appropriations. The reasons which commendably caused the Administration to conduct the essential research should certainly have impelled those who manufacture and utilize the colors to perform the necessary tests to determine whether a hazard to the public health exists. The burden of establishing that a synthetic dye is both harmless and suitable for use is on them.

The only pharmacological evidence bearing on the question whether the colors here involved can be said to meet the standard of harmlessness was that presented by Dr. Bert J. Vos, Assistant Chief of the Division of Pharmacology of the Food and Drug Administration. There is no need to dwell in this brief upon his testimony, which was not contradicted in any respect. His testimony, and the [fol. 61] data which he submitted, disclose that all three dyes possess a degree of toxicity which removes them from the category of "harmless."

The findings set forth the results of the laboratory work performed by the Food and Drug Administration, and reveal beyond any doubt that the colors cannot be said not to present a hazard. Our brief submitted at the conclusion of the hearing, to which we refer and request that it be considered in this connection as constituting part of this brief, makes detailed references to the evidence of record amply supporting the findings of the Acting Secretary. Finding of Fact 3, predicated upon the uncontradicted evidence of record, indicates quite glaringly the adverse physiological consequences of the ingestion of the colors by test animals. The evidence entirely supports the finding that the colors are not harmless but on the contrary are definitely toxic and exert pronounced physiological effects on body tissue. It appears to us that one must possess a high degree of temerity to urge, after a consideration of these findings, that these dyes should nevertheless be employed in or on any foods in amounts smaller than those fed to the laboratory animals. The more pertinent question is why

these colors, performing not the slightest service to the consumer, were continued in use by their manufacturers although doubt as to their toxicity and carcinogenicity has existed for some time.

Particularly is this true in view of the fact that carcinogenicity tests have not been completed. Certainly the Secretary cannot shut her eyes to what is scientifically accepted, and that is that coal-tar colors are suspect with respect to their effect in causing cancer, that a cancer [fol. 62] produced by a substance such as a coal-tar dye may not reveal itself for many years and may be caused by minute amounts, and that no comprehensive work has been performed to determine even with a reasonable degree of certainty whether the three coal-tar colors here involved are or are not carcinogenic. It is true that these colors were once approved and that the burden of going forward with evidence pertaining to harmlessness may be on the Government. But the burden of proof never changes—under Section 406(b) the burden is on those who wish to market a coal-tar color to establish that it presents no hazard, and particularly from the viewpoint of carcinogenicity. The failure to perform any work of this vital character or to present an iota of evidence at the hearing tending to establish the freedom of the colors from cancer producing consequences or other hazard would of itself be sufficient to demonstrate that the dyes have not been shown to be harmless. The Secretary may certainly take notice of a plethora of scientific testimony bearing on this cancer problem. One example is that given by Dr. Francis E. Ray, Director, Cancer Research Laboratory, University of Florida, at the Hearings held before the House of Representatives Committee to Investigate the Use of Chemicals in Food Products, Eighty-First Congress, Second Session. This is what Dr. Ray said, in part, at page 641, on the over-all problem of the possible cancer-producing quality of the synthetic coal-tar dyes:

"A whole series of the class known as AZO Compounds related to the dye, butter yellow, have been found to produce cancer. According to the twenty-sixth annual report of the British Empire Cancer Campaign (p. 198) two food dyes in general use containing the AZO group [fol. 63] were examined. One of these, oil orange E,

caused tumors in 7 out of 17 mice, 14 months after the start of the experiment—14 months is about half the life of a healthy mouse. An eighth mouse showed extensive liver damage.

"I would suggest to the committee that we have not adequately tested our so-called certified pure-food colors for carcinogenic properties. These substances should be tested by feeding, painting, and injection for a period of at least 18 months. Each animal should be examined both grossly and microscopically by a competent pathologist."

We contend that it is somewhat disingenuous under these circumstances, to state that "There is, however, no evidence that, in the amounts used, and in the manner of use, in the coloring of citrus fruit, the product so colored is not safe for human consumption".[1] We urge that any statement, particularly if it emanates from the Government, whereby an impression is created that the colors or foods containing them are safe, is an unintended disservice to the public. True, the evidence does not establish beyond any doubt that these dyes have been shown to have caused injury to man. But as Finding of Fact 3 itself points out, the most that can be said in this connection is that:

"The experimental work on man is limited, and except for Orange 1, adverse effects on man *have not been definitely confirmed*" (Italics supplied.)

[fol. 64] And if anything is well-settled in food and drugs law, it is that Sections 403(a) and 201(n) of the Act prohibit statements which are misleading even though not literally false. See United States v. 95 Barrels of Vinegar, 265 U.S. 438, 442-443. The very purpose of Section 201(n) of the Act is to prohibit deceptions of this character, and a statement that the colors have not been demonstrated to be harmful to humans in the amounts utilized, without coupling it with a statement of the fact that the colors are poisonous or deleterious (and therefore not harmless) substances is at best deceptive and a

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[1] See letter dated February 7, 1955, from the Commissioner of Food and Drugs to Senators Holland and Smathers.

failure to reveal a material fact. The misleading impression created by the sentence quoted above (which can with such facility be taken out of context) is not appreciably weakened by preceding the sentence with a statement that "Recent investigations show that these colors, when fed in substantial amounts, show evidence of toxicity." We urge most seriously, therefore, that steps be taken to dispell such misleading impression—otherwise the high standard of truth called for by the Act has not been met. See, for example, United States v. 12 Bottles of Esterex (E.D. Mo., 1946), Kleinfeld and Dunn, "Federal Food, and Cosmetic Act, 1938-1949", p. 523. In that case, a solution of monochloracetic acid, which the Government regarded as a poisonous or deleterious substance, was shipped in interstate commerce. Its labeling did not contain any false statement, but it was the Government's position, under Sections 403(a) and 201(n) of the statute, that the labeling was misleading in that it failed to reveal the fact that the article contained a poisonous substance, and that such a fact was material in the light of the representation that the article was to be employed as a [fol. 65] component of food. In accepting the Government's position and condemning the product, the Court found, in part:

"There is nothing on the label to indicate that monochloracetic acid is poisonous, and the label does not sufficiently caution the careless, the unthinking or the ignorant of the fact that the said article contains a poisonous, toxic and caustic substance. • • •

"Although there is no statement on the label which is untrue, the label is misleading in that it fails to reveal that the said article contains a poisonous, toxic and caustic substance and such fact is material in the light of the representations that said article is to be used as a component of liquids for human consumption."

On the basis of the Government's own experimental work, it cannot be said, without creating a misleading impression, that there is no evidence that oranges containing the dyes are not safe for consumption. Can it be said, rather, that citrus fruit containing the dyes are safe for human consumption? The only statement which would be fair to the public, both here and abroad, would be one which

would say in substance: "The coal-tar colors are poisonous substances and therefore cannot be said to be harmless. We are suspicious, but so far it has not been established beyond doubt that these dyes, in the amounts used in foods, including oranges, have caused injury to humans. We cannot say that they have not caused damage, and we are continuing our experimental work." Particularly should this be true in view of the fact that the present proceedings have been brought to decertify colors which have been [fol. 66] widely used for many years with Governmental clearance and approval notwithstanding that they are not harmless substances.

II

The criterion of Section 406(b) is whether a coal-tar dye is a harmless substance, and not whether the amount added to a food results in the food being rendered harmful to health.

In connection with the interpretation of a law such as the Federal Food, Drug, and Cosmetic Act, designed to protect the public health, there is no reason for an unnecessary limitation of the protection afforded to the consumer by the plain language of the statute. United States v. Dotterweich, 320, U.S. 277. Section 406(b) of the Act provides, in explicit language, that "The Secretary shall promulgate regulations providing for the listing of coal-tar colors which are harmless * * *." If Congress had intended to say that the Secretary shall promulgate regulations providing for the listing of coal-tar colors "which, in the amount used in a food, are harmless for use in such food", or "which, in the amount used in a food, do not render the food harmful", Congress would have said so, the words were readily available.

It is apparent, from both the specific language of subsection (a) of Section 406 and the pertinent legislative history, that the Congressional design was to exclude from the Nation's food supply poisonous and deleterious substances in any amount whatever unless they are required in or can not be avoided by good manufacturing practice, and to establish tolerances for such poisonous or delterious [fol. 67] substances when they are so required or can not be so avoided. Subsection (b), which is in pari materia

with subsection (a), similarly prohibits the employment in food of any coal-tar color which cannot be demonstrated to be a harmless substance. The only distinction between the two subsections is that Congress chose not to permit the establishment of any tolerances for harmful coal-tar colors such as are here involved, apparently because there was no proof whatever that dangerous coal-tar dyes are required in the production of any food or cannot be avoided by good manufacturing practice.

In our brief submitted after the conclusion of the hearing, we adverted at considerable length to the legislative history of the Act, which reveals beyond any doubt the design of Congress to prohibit entirely those coal-tar colors which cannot be considered, regardless of amounts employed, to be harmless substances, and not proscribe merely the employment of such quantities as might render the particular food containing the color harmful to health. We also discussed the unvarying administrative position of the Food and Drug Administration, and the judicial holdings, which are in complete accord with the language and legislative history of the Act. We respectfully refer to our prior brief as if the applicable portions, in this connection, were set forth here in full.

Philosophy of the Act

The entire philosophy of the Federal Food, Drug, and Cosmetic Act envisages the proscription from the dietary of the Nation of all amounts of substances which are or [fol. 68] may be harmful, with the specific, limited exception contained in Section 406(a). For example, in Statement of General Policy or Interpretation, Section 3.14, dated January 13, 1950 (Kleinfeld and Dunn, "Federal Food, Drug and Cosmetic Act, 1949-1950," p. 285), the Federal Security Administrator announced that he regarded dulcin and P-400, artificial sweeteners, as poisonous substances which had no place in any food. This position was taken in view of the effect of the ingestion of the substances by rats, notwithstanding that it had not been established that the ingredients produced toxic effects in humans in the amounts customarily employed in foods.

The same problem was recently highlighted in connection with coumarin, which had been used for many years

as a food flavor without any indication that it was injurious. After a public hearing which revealed that coumarin had produced toxic results in test animals, the Department of Health, Education, and Welfare removed the substance as an optional ingredient for use in cacao products, notwithstanding that there was no evidence that, in the amounts in which it was employed in food, it produced any adverse physiological effects in humans.

There would seem to be no need for laboring the point unduly. It is apparent that Congress deliberately provided against the utilization of any amount whatever of a coal-tar dye which, standing by itself, cannot be said to be harmless. The reason for this, and for the similar result which follows where Sections 401 and 406(a) are involved, are obvious. Substances which are or may be dangerous should [fol. 69] not be inflicted upon the consuming public in any amounts. Even if it is probable that a small amount of a poisonous or harmful substance such as the coal-tar dyes may not cause harm in a comparatively short period of time, there is no assurance that its ingestion over long periods of time, and the consumption of small amounts of other and diverse poisonous, dangerous, or harmful substances, will not cause carcinogenic or other adverse physiological effects. The soundness of and necessity for this approach were set forth most eloquently in December of 1952 by the United States Court of Appeals for the Third Circuit in Atlas Powder Company v. Ewing, 201 F. 2d 347. In that case, the petitioners sought review of an order establishing a definition and standard of identity for bread which did not permit the use of petitioners' chemical softeners. There was no proof that, in the amounts in which the softeners were employed in bread, harm resulted to humans. Nevertheless, the Federal Security Administrator concluded that the softeners could not be used in bread because the results of their ingestion by test animals revealed that the safety of the substances had not been established. As stated, the Administrator could not determine (as the Secretary cannot determine with respect to the use of coal-tar colors on oranges) that, in the amounts utilized in bread, the softeners were deleterious to the health of humans. In affirming the decision of the Administrator, however, the Court set forth the rationale which is a fortiori applicable to coal-tar colors:

"One making a rule for the future which in practical effect will determine whether millions of people shall eat something every day may reasonably refuse to subject [fol. 70] the general public to even slight risks and small deceptions. In these circumstances, the fact that administrative action has been dominated by great caution but serves to emphasize the reasonableness of the Administrator's conduct."

Use of the Colors in Oranges

It is well-known that orange juice from Florida oranges is consumed practically every day by large numbers of persons in this country, that marmalades frequently contain orange rind, that candied orange peel is consumed, and that in baking cake some women grate the rind to obtain additional flavor.

Mr. Louis C. MacDowell, Research Director of the Florida Citrus Commission, testified (R. 101, 102) with respect to the quantities of coal-tar dyes found in whole fruit, orange peel, candied orange peel, orange marmalade and orange juice. The amount of coal-tar dye found ranged from 17.63 to 24.39 parts per million in the peel of fresh fruit, to .04% to .07% parts per million in orange juice. There is not the slightest basis for any contention that those amounts may be ignored, for we have shown that a coal-tar color which has not been shown to be a harmless substance may not be employed in or on foods in any amount.

Certainly this would seem to be particularly true with regard to oranges, which in one form or another are consumed every day in the year "by the strong and the weak, the old and the young, the well and the sick". (See United States v. Lexington Mill and Elevator Co., 232 U.S. 299). As we have demonstrated, Congress did not provide, in [fol. 71] Section 406(b), for the taking of any chances with the health of the inhabitants of this country. None should be taken with a synthetic dye, for example, which from a chronic viewpoint has greater toxicity in rats than carbolic acid and whose freedom from hazard, including carcinogenicity, has not been established. Even if there were any provision in subsection (b) for the making of exceptions, and the subsection contains none, the exception should not be made in connection with the use of the three coal-tar dyes

here involved on oranges, consumed by all segments of the population, and in all degrees of health. This is particularly true since there is not an iota of evidence that the dyes serve any useful purpose whatever or that their addition to oranges does not defraud the consumer, conceal inferiority, or make the product appear better and of greater value than it actually is.

III

A coal-tar color may not be listed as "suitable for use" under Section 406(b) if it violates other provisions of the Act.

Section 406(b) provides that the Secretary shall promulgate regulations providing for the listing of coal-tar colors which not only are "harmless", but also are "suitable for use", in food. Regardless of the question of toxicity, we cannot comprehend how, under a remedial statute such as the Federal Food, Drug, and Cosmetic Act, clearly designed to protect the consumer, it can be maintained that a coal-tar dye can be said to be suitable for use on oranges unless it is demonstrated that the consumer is not being [fol. 72] deceived and that the Act is not otherwise violated. We urge that evidence with respect to any coal-tar color used or proposed for use in foods must be presented to the Secretary, and findings made by her, as to whether the dyes do or do not conceal inferiority, do or do not make the food appear better or of greater value than it is, and do or do not constitute a fraud upon the consuming public. Only upon the basis of such evidence, as well as upon evidence of harmlessness, can the Secretary comply with the Congressional directive, in Section 406(b), that in order for coal-tar colors to be listed they must be harmless and suitable for use.

By letter dated October 13, 1952, addressed to Mr. Randall Chase, the Associate Commissioner of Food and Drugs stated in part:

"Let me say at the outset that this Administration is in agreement with your conclusion that the use of added color on oranges is inherently deceptive and is contrary to the interests of both consumers and producers."

We are in entire accord with that administrative position. We are in disagreement, however, with the view apparently

taken at that time that the legislative history of the Act requires a conclusion that the law does not ban the use on oranges of such dyes as create an economic cheat upon the consumer. We believe it would take specific language indeed to indicate a Congressional intent to permit the use on oranges of any coal-tar color which "is inherently deceptive and is contrary to the interests of both consumers and producers." We are not contending that [fol. 73] no coal-tar dye may be used under any circumstances, for Section 402(c) does make a reference to the employment of color on oranges. But nothing in the Section, or in the legislative history reveals a design to permit the use of those dyes which clearly violate the explicit provisions of the statute dealing with the adulteration and misbranding of food products. Contrariwise, as we shall demonstrate, what there is in the legislative history leads to the opposite conclusion.

1

A separate finding must be made with respect to whether a coal-tar dye is "suitable for use."

No citation of authorities is needed to support the virtually universal maxim of statutory construction that words are not inserted in a law for no purpose. The term "suitable for use" cannot refer to the harmlessness of a coal-tar dye, for such a construction would add nothing to the word "harmless" and render "suitable for use" superfluous. The phrase, therefore, must refer to something other than hazard to health. Again, considering the remedial purposes of the Act, stressed again and again by the executive branch, as well as by the judicial and legislative branches, of our Government, "suitable for use" must be construed to refer to economic protection of the consumer.

Under Section 406(b), "suitable for use" is as much a prerequisite to approving a coal-tar color as is "harmless". Findings dealing with both aspects must, therefore, be made by the Secretary—otherwise the statutory mandate [fol. 74] is not observed and the judicial review provided by the Act cannot be obtained. As stated in Twin City Milk Producers Association v. McNutt, 122 F. 2d 564 (C.A. 8), "But where a Court is charged with the duty of reviewing the validity of an administrative agency's order, it has, up to the present time at least, refused the stamp of judi-

cial approval, unless the order affirmatively demonstrated a compliance with all express and implied conditions underlying the exercise of the power." See, also, A. E. Staley Manufacturing Co. v. Secretary of Agriculture, 120 F. 2d 258 (C.A. 7).

2

The Act does not authorize the listing of a coal-tar color whose use will violate specific statutory provisions.

As we have pointed out, there is no indication that, by utilizing the language found in Section 402(c), Congress intended to extend a blanket authorization to orange growers to conceal the inferiority of their product, deceive the consumer, and make their product better and of greater value than it is.

There is nothing persuasive in the legislative history of the Act which reveals any design to permit a defrauding of the consumer. As a matter of fact, at one step of the progress in Congress of the various bills which culminated in the passage of the statute, a specific attempt was made to authorize the coloring of oranges notwithstanding the adulteration and misbranding provisions of the law. When S. 2800, 73d Congress, was reported out by the Senate Committee on Commerce, the following paragraph was added:

[fol. 75] "Nothing in this Act shall be construed to prohibit the enhancement of the color of mature and wholesome citrus fruits to the varietal color thereof, by means harmless to the consumer of such fruits, nor to require any declaration of such enhancement, by labeling or otherwise." (Dunn, "Federal Food, Drug, and Cosmetic Act," p. 94.)

A subsequent reprint of the bill with Committee Amendments contained the same provision. (Dunn, supra, p. 169.)

It will be seen, therefore, that Congress gave definite thought to permitting the use of coal-tar dyes on oranges notwithstanding the resulting economic cheat of consumers. In fact, Congress even gave consideration to not requiring that the addition of the color be declared on the labeling of the food containing it. If the language quoted above had been retained, it might be argued that any coloring, even if a food containing it would otherwise have been

misbranded under Section 403(a), and adulterated under Section 402(b), could be utilized. Nor would Section 403 (k), requiring a declaration of the presence of artificial coloring, have been applicable. But Congress chose not to include the quoted provision, not to permit the use of those colors which would act as a fraud upon the public; just as Congress determined to retain the applicability of Section 403(k). The legislative history, therefore, requires the construction that coal-tar dyes which are harmless may be employed, but only if they do not contravene any other provisions of the Act. The burden of establishing that the relevant statutory provisions will not be violated, that the consumer will not be defrauded, has not been [fol. 76] met in the slightest respect by those who seek to employ coal-tar colors on oranges. It is well-settled that economic adulteration cannot be cured by any form of labeling. United States v. 2 Bags * * * Poppy Seeds, 147 F. 2d 123 (C.A. 6); United States v. 36 Drums "Pop'n Oil", 164 F. 2d 250 (C.A. 5). Since the Government has recognized that the use of the colors on oranges is "inherently deceptive", no labeling can be legal. Assuming for the sake of argument, however, that some form of truthful labeling would be permitted (although none should be), Sections 403(a) and 201(n) would require a declaration that the dye had been added to conceal inferiority.

3

Section 403(k) does not authorize the introduction into interstate commerce of a citrus fruit containing a dye which conceals the inferiority of the fruit and makes it appear better and of greater value than it is.

The heating and dyeing of an orange with a coal-tar color is a chemical process designed to imitate natural maturity. Its purpose is to conceal immature skin and other inferiority, to disguise blemishes, and to add a deeper color to the naturally pale color of the orange for the purpose of causing the consumer to think he is getting a naturally tree-ripened fruit. To a very considerable extent, the consumer makes purchases on the basis of the color and external appearance of the orange, and color is one of the considerations in grading the fruit. As indicated above in this brief, the economic cheat caused by adding a dye to oranges has been recognized by the Food and Drug

Administration. Certainly the use of these colors does not [fol. 77] add any food value to the fruit or benefit the consumer in the slightest respect.

The legislative history of the Federal Food, Drug, and Cosmetic Act discloses that, in inserting Section 403(k), which permits the addition of artificial coloring if the food containing it bears labeling stating that fact, it was the Congressional intent to ban the transportation in interstate commerce of products which had been adulterated by the addition of artificial coloring. The predecessor of Section 403(k) appeared in S. 5, 74th Cong., 1st Sess. As reported by the Committee on Commerce, Section 302(k) of the bill (which later became in substance Section 403(k)), declared a food to be misbranded—

"If it bears or contains any artificial flavor, artificial color, or chemical preservative, and it fails to bear a label stating that fact."

The Committee report on the bill said of this provision:

"Paragraph (k) is intended to insure label declaration of additions of artificial color, artificial flavor, or chemical preservatives. This paragraph does not exempt products subject to it from the other provisions of the bill. *If artificial color is harmful or creates a deceptive appearance, the product will be subject to the applicable provisions* of Section 301 [the adulteration section which included the counterpart of Section 402(b)(3) and (4)]" (Italics supplied) (S. Rep. No. 361, 74th Cong., 1st Sess., p. 13.)

[fol. 78] Before the bill passed the Senate, Section 302(k) was amended to read:

"If it bears or contains any artificial flavor, artificial color, or chemical preservative, which is not prohibited by section 301, and it fails to bear a label stating that fact."

Section 301 defined a food as adulterated—

"* * * (3) If damage or inferiority has been concealed in any manner; or (4) if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or create a deceptive appearance."

When this bill was reported by the House Committee, the words "which is not prohibited by section 301" were deleted. The Committee's explanation was as follows:

"Section 302(k): In this paragraph the words 'which is not prohibited by section 301' were omitted as being sur-

plusage, and furthermore their presence created confusion as to the meaning of the words 'stating that fact' which appear later in the paragraph (H. Rep. No. 2755, 74th Cong., 2d Sess., p. 5.)"

Implicit in the explanation of the House Committee is its agreement with the expression of legislative design in the excerpt from the Senate Report.

It is entirely clear, therefore, that the Congressional intent in enacting Section 402(b) and Section 403(k) was to prescribe two separate prohibitions, each essentially dif-[fol. 79] ferent from the other. The authority in Section 304(k) to use artificial coloring, artificial flavoring, and chemical preservatives is limited to those products whose inferiority is not concealed, and which are not made to appear better or of greater value than they are, by the addition of an artificial ingredient. This legislative motivation is consonant with the objects of the Act "to prevent the misuse of the facilities of intersate commerce in conveying to and placing before the consumer misbranded and adulterated articles * * *". McDermott v. Wisconsin, 228 U.S. 115, 131. This construction of Sections 402(b) and 403(k) has been invariably urged by the Food and Drug Administration, and the Courts have accepted this interpretation. See, for example, United States v. Two Bags * * * Poppy Seeds, 147 F. 2d 123 (C.A. 6), where the Court sustained the Government's contention that the addition of charcoal pigment to white poppy seeds so that they resembled more expensive seeds, the product then being shipped to jobbers truthfully labeled under Sections 403(a) and 403(k), concealed inferiority and made the product appear better or of greater value than it was, in violation of Section 402(b).

4

Under Section 406(b), no distinction can be made between oranges and other foods.

We have pointed out that Section 406(b) proscribes any amount of a substance which has not been demonstrated to be a harmless, non-poisonous substance, even if it has not been established that the amount contained in a particular food will cause harm to humans. The amount of the coal-[fol. 80] tar dyes found in the juice of oranges and in the peel does not alter this concept in any respect, particularly

since, as we have stated, orange juice is consumed every day by all segments of the population, including babies, children, the aged and infirm. If the colors were permitted on oranges, although there could not be the slightest legal justification for such authorization, the provisions of Sections 403(a) and 201(n), as construed by the Food and Drug Administration and interpreted by the Courts, would require that the consuming public be informed not only of the material fact that the dye conceals inferiority, but also of the material fact that the color is a poisonous substance. See United States v. 12 Bottles of Esterex, supra. The orange would be compelled to declare "Artificial coal-tar color, a poisonous substance, added to conceal inferiority." In this connection, we believe we should direct attention to the fact that the term "color added", as presently employed on oranges to which a coal-tar dye has been added, cannot be said to comply with the provisions of Section 403(k). The Section does not state that:

"A food shall be deemed to be misbranded—If it bears or contains any flavoring, coloring, or preservative, unless it bears labeling stating that fact * * *." Rather, the section is specifically directed at the addition of artificial or synthetic substances; thus it provides quite clearly that:

"A food shall be deemed to be misbranded—If it bears or contains any *artificial* flavoring, *artificial* coloring, or chemical preservative, unless it bears labeling stating that fact * * *." (Italics supplied.)

[fol. 81] It is apparent, therefore, that Section 403(k) requires labeling which informs the consumer that an artificial color has been added, that the phrase "stating that fact" refers to the fact that an artificial substance has been employed, and that it is violative of the Act and a disservice to the consuming public to permit the use of wording such as is currently found on oranges containing a synthetic coal-tar dye.[2]

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[2] See S. Rep. No. 361, 74th Cong., 1st Sess.: Paragraph (k) is intended to insure label declaration of additions of artificial color, artificial flavor, or chemical preservatives." (Dunn, supra, p. 248.) See also S. Rep. No. 91, 75th Cong., 1st Sess.:

> "Requires label declaration of artificial colors and artificial flavors in food." (Dunn, p. 680.)

Conclusion

The record of the hearing fully supports the findings that FD&C Orange No. 1, FD&C Orange No. 2, and FD&C Red No. 32 are not substances which have been shown to be harmless for use in or on any food, including oranges. Consequently, for this reason alone, colors may not be permitted use in the dietary of the Nation and Section 135.3 of the color certification regulations should be amended, as set forth in the proposed order, by deleting the names of the three dyes and the respective specifications therefor.

The findings and order should make a determination, in addition, with respect to whether the colors involved and any other colors referred to are suitable for use in that they do not conceal inferiority, or make a food appear better or of greater value than it is, or otherwise deceive the consumer, in violation of Section 402(b). No label [fol. 82] declaration can cure such economic adulteration, but any statement purporting to comply with the provisions of Sections 403(a) and 201(n), as well as with 403(k), should be an honest and truthful one. Labeling is not honest and truthful, and does not comply with the statute, if it does not reveal that there has been added to the orange a substance (assuming it is harmless) which (1) is an artificial coal-tar dye, and (2) is designed to conceal the inferiority of the orange and make it appear better and of greater value than it is.

Respectfully submitted, Chase & Company, Randall Chase, Vincent A. Kleinfeld, Counsel.

1052 Pennsylvania Building, 425 Thirteenth Street, N. W., Washington 4, D. C.

Before the Department of Health, Education and Welfare
Food and Drug Administration

In the Matter of: Color Certification

Docket No. FDC-60.

EXCEPTIONS OF COAL-TAR COLOR INDUSTRY COMMITTEE

The Coal-Tar Color Industry Committee, whose members produce 90% of the coal-tar colors produced in the United States for use in foods, drugs and cosmetics, [fol. 83] make 3 types of exceptions to the proposed order concerning FD&C Orange No. 1, FD&C Orange No. 2 and FD&C Red No. 32 (hereinafter referred to as "Orange 1", "Orange 2" and "Red 32", respectively) published at pages 9352 and 9353 of the Federal Register of December 30, 1954. These types of exceptions are:

1. The basic exception that the order does not comply with the statutory mandate.

Denied.

2. Exceptions for failure to make certain factual findings which are fully supported and wholly uncontradicted by the record.

Allowed in Part. See specific exceptions infra.

3. Exceptions based upon the fact that the proposed findings do not truthfully or accurately reflect the record, and that such proposed findings are incomplete, exaggerated and distorted.

Allowed in Part. See specific exceptions infra.

I

Basic Exceptions

1. The proposed order is not based on substantial evidence of record as required by Section 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 371(e)).

Denied.

[fol. 84] 2. The last paragraph of the Secrteary's Proposed Finding of Fact 3, appearing in the first column of page 9353 of the Federal Register of December 30, 1954, should be changed to read as follows (new matter is in italic; deleted matter is stricken through):

"The results of pharmacological tests, conducted by qualified investigators using recognized scientific methods, established that the colors are ~~not~~ harmless substances *in the quantities in which ordinarily used or in quantities in which their use can be reasonably anticipated,* ~~but on the contrary are definitely toxic and exert pronounced physiological effects on body tissue. The experimental work on man is limited, and except for Orange 1 adverse effects on man have not been definitely confirmed.~~":

Denied. (Findings changed, but substance objected to remains.)

3. In light of the suggestions made above and those made hereafter, Findings of Fact 4 and 5 in the Secretary's Proposed Order are unnecessary and should therefore be deleted.

Denied.

4. Conclusion 1 of the Secretary's Proposed Order should be modified by deleting the word "not" before the word "harmless".

Denied.

5. In Conclusion 2 of the Secretary's Proposed Order, [fol. 85] the word "not" should be inserted between the word "should" and the words "be deleted", and the following matter in proposed Conclusion 2 should be deleted:

"since the Secretary cannot continue to list these colors as colors that the Food and Drug Administration will certify as harmless and suitable for use in coloring food or in coloring drugs and cosmetics intended for other than external application."

Denied.

6. In light of the proposed changes suggested above, Conclusions 3, 4 and 5 of the Secretary's Proposed Order become unnecessary and should be deleted, and the proposed amendment of Part 135 of the Color Certification Regulations becomes unnecessary and should therefore be deleted.

Denied.

II

Exceptions Based Upon Failure to Find Uncontroverted Facts

Exception is taken to the Secretary's failure to make the following findings all of which are fully supported and wholly uncontradicted by the record. (For convenience, the transcript of testimony is hereinafter referred to as "R".)

1. The following tests, with the results indicated, were [fol. 86] conducted by the Division of Pharmacology of the Food and Drug Administration of the government of the United States of America:

(a) Orange 1.

i. In the two-year period 1939-1940, twenty rats were fed on a diet containing 0.1 percent Orange 1. No significant effect on growth or mortality was observed, and no effect was observed in the gross and microscopic examination of the animals (R. 14).

Allowed in Part. See Finding 4.

ii. In the five-year period 1938-1943, three dogs who were fed capsules containing 5 milligrams of Orange 1 per kilogram of body weight per day appeared in satisfactory condition throughout the experiment and were sacrificed at the end of 61 months to terminate the experiment. Pathological examinations of these dogs showed nothing which could be attributed to the color (R. 16-18).

Allowed in Part. See Finding 4.

(b) Orange 2.

i. For a period of two years beginning in 1939, 24 rats were placed on a diet containing 500 parts per million of Orange 2. A second group of 24 rats received the same diet without the added color in a parallel 2 year experiment. Groups of 18 rats were fed 500 parts per million and 100 parts per million of Orange 2 mixed in a low-protein diet, and a third group of 18 rats received the low-protein diet alone.

[fol. 87] Allowed in Part. See Finding 5.

There was no effect on mortality as a result of feeding Orange 2 at these two levels.

There were changes in the hearts of the animals which had received 500 parts per million of Orange 2 in their diet; but only in the case of two animals at the 100 parts per million level was there a suggestion of certain other changes (R. 23-24).

ii. In an experiment begun in 1938 one dog received 100 milligrams per kilogram per day given as an oil solution by a period of about 11 months. Following this the dose was reduced to 20 milligrams per kilogram per day and was continued for 60 months. A second dog was started on 100 milligrams per kilogram per day given as an oil solution by stomach tube for about a month. The dose was then reduced to 20 milligrams per kilogram per day for about a month, and finally to 5 milligrams per kilogram per day administered in capsules. This dose was continued for 62 months.

Allowed in Part. See Finding 5.

In the case of the first dog the dose was reduced from 100 milligrams because the dog was in poor condition as a result of this dose. When the dose was reduced to 20 milligrams per kilogram per day the color was tolerated and the dog gained weight. It was sacrificed in good condition after 60 months on this dose. The dose in the second dog was reduced, first from 100 milligrams per kilogram per day to 20 milligrams per kilogram per day, and finally to 5 [fol. 88] milligrams per kilogram per day, because the dog was not eating well, and was gaining weight slowly on the higher doses. The 5 miligrams per kilogram per day was

tolerated and the dog was sacrificed apparently in good condition after 62 months on this dose.

In this period of time the dog had 6 litters of puppies, which were of average size and health (R. 26-27.)

(c) Red 32.

i. Beginning in 1938, Red 32 was administered to 5 dogs, each of whom received a dose of 5 milligrams per kilogram per day for a period of five to six years. One of these dogs received a dose of 100 milligrams per kilogram per day for approximately a month, a dose which was later reduced to 20 milligrams per kilogram per day for approximately a month. Another dog received 100 milligrams per kilogram per day for about ten months, a dose which was later reduced to 20 milligrams per kilogram per day and continued for approximately five years. All 5 dogs were sacrificed at the end of the five-year period in apparently good condition, though the two dogs which received 100 milligrams per kilogram per day of Red 32 showed moderate weight loss while this dose was being given (R. 35-36).

Allowed in Part. See Findings 7 & 8.

ii. In addition, one of the constituents of Red 32, the para-isomer, was administered to two dogs at a dose of five milligrams per kilogram per day for six years and the meta-isomer was administered to three dogs at a dose of five [fol. 89] milligrams per kilogram per day also for six years. Pathological examinations of the animals following sacrifice showed no changes which could be attributed to treatment (R. 35-36).

Allowed in Part. See Findings 7 & 8.

iii. Experiments in 1940 and 1941 showed that a 0.1 percent concentration of Red 32 in the diet of rats markedly depressed the growth and reduced the median survival time (R. 31).

Allowed in Part. See Finding 7.

2. In its toxicological studies, the Food and Drug Administration attempted to administer the compound under investigation at a series of levels, some of which would produce no effect, some a slight effect, and others a

marked effect. Where the color was given at only one dosage level in the experiment, it would be impossible to achieve all of those ends (R. 42-43).

Denied.

3. The levels at which the dosages were administered in all the tests referred to in the record were not related to the levels of the colors as actually used under normal conditions of use (R. 43).

Denied. See Finding 10.

4. Common table salt could produse harmful effects and a human being would suffer some adverse effects when ingesting 2 or 3 ounces of salt (R. 47-48).

Denied.

[fol. 90] 5. In sufficient quantities any substance might cause adverse reactions (R. 49).

Denied.

6. The amount and conditions of proposed use of a material are necessary data for deciding whether in a pharmacological sense a material is harmless for the use intended (R. 57.58, 60).

Denied. See Finding 10.

7. There is no evidence that Orange 1, Orange 2 or Red 32 would cause harmful effects in quantities used under ordinary conditions of use, except that several years ago a sample of candy containing 700 parts per million (.07 percent)of Orange 1 was collected by the Food and Drug Administration as the result of a complaint that that candy had caused diarrhea in a child. This candy contained 700 parts per million of the dye, an amount greatly in excess of the amount normally used and which constitutes an abuse. Three human volunteers, one of whom ate 6 or 8 pieces of the same candy, one of whom ate 4 pieces and one of whom ate one piece, suffered marked abdominal griping and diarrhea (R. 67-68. .0-21).

Allowed in Part. See Findings 3, 9 & 10.

8. The concentration of dye in color-added oranges ranged from 3.39 to 6.78 parts per million of dye per fruit (R. 101).

[fol. 91] Denied. See Findings 9 & 10.

9. The concentration of dye in the peel of fresh fruit ranged from 17.63 to 34.26 parts per million (R. 101).

Denied. See Findings 9 & 10.

10. The concentration of dye in juice extracted from whole fruit to which color has been added ranged from .04 to .07 parts per million (R. 101).

Denied. See Findings 9 & 10.

11. Candid orange peel had 7.4 parts of dye per million (R. 101).

Denied. See Findings 9 & 10.

12. Orange marmalade had 1.8 parts of dye per million (R. 102).

Denied. See Findings 9 & 10.

13. One of the products produced by Kline & French Laboratory contains Orange 1 to extent of 2 micrograms per recommended daily dose. This is 1/4,000,000 of the 1,000 parts per million (.1 percent) (see Proposed Finding II 1(a) i., above) fed to rats by the Food and Drugs Administration over a two-year period and found to produce no effect (R. 103).

Denied. See Findings 9 & 10.

14. The 2 microgram per day dosage referred to in Proposed Finding 15 above is 1/200,000 of the 5 milligrams [fol. 92] per kilogram of Orange 1 fed to dogs by the Food and Drug Administration (see Proposed Finding II 1(a) ii., above) for 62 months and found to have had no effect (R. 103).

Denied. See Findings 9 & 10.

15. Another of the products of Kline & French Laboratory contains Red 32 to extent of 30 to 35 micrograms per

daily dose. This is 1/10,000 of the dose of 5 milligrams per kilogram a day fed to dogs by the Food and Drug Administration (see Proposed Finding II 1(c) i., above) in a 5-year experiment and found to produce no effect (R. 103-104).

Denied. See Findings 9 & 10.

16. The amount of dye used in the Kline & French Laboratory products described in Proposed Findings 15 through 17, inclusive, above, is indicative of the relative amounts of those dyes commonly used in pharmaceutical prepartions (R. 104).

Denied.

17. The amount of dye in pharmaceutical products is normally of the order of magnitude ranging from 2 to 35 micrograms per recommened daily dose (R. 105).

Denied.

18. The Food and Drug Administration has taken cognizance of the differing orders of toxicity of coal-tar colors by providing at least 3 classifications for these colors, [fol. 93] namely, FD&C, D&C, and External D&C (R. 104).

Denied.

19. The total weight of a 1408 calory reducing diet is 1172 grams (R. 117).

Denied.

20. The amount of food purchased at retail in the United States per individual in the period 1909-1952 was above 1500 pounds per year in all years but two, where the amounts purchased equalled 1499 and 1494 pounds. This corresponds to approximately 1800 grams of food per day (R. 117-118).

Denied.

21. The average human diet in the United States is between 1 kilogram and 1500 grams per day (R. 118).

Denied.

III

Exceptions Based upon Inaccuracies and Distortions Contained in Secretary's Proposed Findings

While the Committee does not believe that the Secretary's Proposed Findings are relevant or material, if such findings are to be made, the Committee believes that they should honestly reflect the record.

[fol. 94] On that basis, the Committee has set forth in separately-lettered paragraphs below the Secretary's Proposed Findings, striking out the matter which it believes is not supported by the record, and in italics matter which it believes must be added to accurately state the record:

A. "Findings of Fact * * * 1. After a hearing held beginning February 6, 1939, * * (R. 46)"—No exception.

Allowed.

B. "2. ~~Because of advances in knowledge and techniques in the field of pharmacology, the Food and Drug Administration has initiated new tests to explore more fully the toxicity of the certifiable coal-tar colors. This involves the application of all techniques and procedures now considered necessary to assure proper evaluation. A number of these tests, with present-day techniques and procedures,~~ have been conducted by the Division of Pharmacology of the Food and Drug Administration, using FD&C Orange No. 1, FD&C Orange No. 2, and FD&C Red No. 32."

There is no testimony in the record, aside from the fact that some tests are more recent than others, to support the words stricken above.

C. "Tests that have been terminated are: * * *

"Tests that were still in progress at the time of the hearing were: * * *

[fol. 95] "Tests of the three colors by external application * * * Ex. 2, 3, 4)."

Allowed in Part. See Findings 2-8.

It is proposed that this matter be deleted at this point in the Proposed Finding, and that each test be discussed

separately, together with the results thereof. This will eliminate redundance, confusion and error. Specific exception, however, is taken to those portions of the Secretary's Proposed Findings which refer to carcinogenicity tests on the ground that such references are immaterial, irrelevant, inflammatory and highly prejudicial, since the record shows the results of those tests were not positive, and on the further ground that in the absence of the added findings -hat the results of such tests were not posi-ive, -he erroneous inference might be made that the colors are carcinogenic (R. 16, 26, 35).

D. "3. ~~The tests that have been concluded are tests normally employed to determine the toxicity of substances taken internally by man. The result of those investigations~~ *the concluded tests* show that each of the coal-tar colors FD&C Orange No. 1, FD&C Orange No. 2, and FD&C Red No. 32, taken internally, caused marked damage to various vital organs of ~~the~~ *certain rats and dogs used as* test animals, significant changes in body weight, and premature death *of such animals when certain large dosages of such colors, as specified below, were administered. Such large dosages were not related to the levels of the colors as actually used under normal conditions of* use."

[fol. 96] The matter deleted is unsupported by the record except in those cases where deletion is grammatically required by the change in substance. The added matter makes the phraseology more precise, is in accord with the Exhibits, and is supported by the testimony at R. 43.

Allowed in Part. See Findings 2-8.

E. ~~"FD&C Orange No. 1 caused the premature death of all rats on a diet containing 2.0 percent of the test substance. In rats on a diet containing 1.0 percent of this substance there were marked~~ *retardation of growth,* ~~increased mortality, and chronic congestion and enlargement of the spleen. These same manifestations, to a somewhat lesser extent, were encountered in rats consuming a diet containing 0.5 percent of FD&C Orange No. 1."~~

In 1951-1953, 24 rats were placed on each of three levels of Orange 1, namely 0.5 percent, 1 percent and 2 percent. A similar group served as controls. The results show that there was a marked adverse effect on growth at the 1 per-

cent level, a slight effect on growth at the 0.5 percent level. There was an effect on mortality at all levels. There was moderate to marked anemia at various times on the 0.5 and 1 percent levels. The pathological examination of the animals showed splenic enlargement at the one percent level, some splenic enlargement at the half percent level, and congestion in various organs at the one percent level. (R. 15-16.)

[fol. 97] Denied. See Finding 3.

F. *An experiment began in 1938 and continued until 1943 consisted of administration of capsules containing Orange 1 to dogs. Three dogs received five milligrams per kilogram per day for a period of approximately five years. Two additional dogs received one hundred milligrams per kilogram per day. The dogs which received 5 milligrams per kilogram per day appeared in satisfactory condition throughout the experiment and were sacrificed at the end of 61 months to terminate the experiment.* Dogs consuming 100 milligrams per kilogram per day ~~of FD&C Orange No. 1~~ *were in satisfactory condition through the early part of the experiment, but after about two years the dogs began to lose weight and* died in 26 months and 33 months. ~~They had occasional diarrhea while alive and manifested terminal~~ weight loss. *Diarrhea was noted at the beginning of the experiment in one of the 100 milligram per kilogram dogs, and terminally in another.* ~~Autopsy revealed congestion and atrophy of the liver attributable to the test substance.~~ *Pathological examination of the dogs showed nothing which could be attributed to the color at the 5 milligram per kilogram per day dose. At the 100 milligram per kilogram per day dose, there were liver changes which consisted chiefly of centrolobular liver congestion and atrophy.*

The record, pp. 16-18, fully substantiates the foregoing modification of the proposed finding.

Allowed in Par. See Finding 3.

[fol. 98] G. *In an experiment begun in 1951,* on a diet containing 1.0 percent of FD&C Orange No. 1, *four* dogs exhibited ~~chronic diarrhea, rapid deterioration, and weight loss.~~ *One dog was sacrificed in extremis at 28 days, and one was found dead after 35 days on the diet. These dogs*

had eaten poorly and had lost about 50 percent of their body weight. The remaining two dogs are still surviving. They are maintaining their body weight, and are still on the experiment which has now continued for approximately 24 months. ~~Autopsy revealed muscular dystrophy and testicular and prostatic atrophy. These same manifestations occurred to a lesser extent in dogs on a diet containing 0.2 percent of FD&C Orange No. 1.~~

Allowed in Part. See Finding 3.

In the same period, four dogs were fed 0.2 percent of Orange 1 in their diet. Of these, one was sacrificed in extremis at 85 days, a second at 260 days. They had lost 37 percent and 45 percent of their body weight, respectively, in spite of having eaten well during the course of the experiment. The remaining two dogs on the 0.2 percent level appeared to be in good physical condition at the end of 23 months on the experiment.

Examination of these four doys showed such changes as muscular dystrophy in all four, marked testicular and prostatic atrophy in the two males, varying degrees of atrophy in several other organs, bone marrow depletion in 3 of the 4 dogs, and additional changes.

The suggested modifications are supported by the testimony at R. 18-19, 39.

[fol. 99] H. ~~A single dose of 100 milligrams to 200 milligrams of FD&C Orange No. 1 produced diarrhea in most dogs.~~ *An experiment conducted in 1952 consisted of administering 200 milligram capsules of Orange 1 to dogs which had been fasted overnight. 11 of 16 animals which were tested developed diarrhea in a period of 4 to 8 hours after receiving the dye. When a dose of 100 milligrams of Orange 1 was administered to 10 of these 11 dogs, 7 responded with diarrhea, two were negative, and one was doubtful. An additional experiment was conducted which 200 milligrams of Orange 1, dissolved in 100 milliliters of water, was administered to 5 of these dogs by stomach tube. All 5 of them responded with diarrhea.*

Denied.

The suggested modification conforms to the testimony at R. 19-20.

I. *Several* human volunteers taking 80 milligrams to 100 milligrams of *Orange 1* in a single dose experienced marked griping and diarrhea (see R. 21).

Denied.

J. *In an experiment begun in 1940, 10 rats were fed a diet containing a 0.1 percent concentration of Orange 2 for 8 weeks after which the concentration was increased to 0.2 percent. In a succeeding experiment, five rats were given a diet containing 0.1 percent of Orange 2 and ten rats were given a diet containing 0.25 percent of the color. Additional 5 animals served as controls and received a diet without* [fol. 100] *added color. These experiments indicated* that FD&C Orange No. 2 caused severe growth retardation and increased mortality to rats on a diet containing 0.25 percent of the test substance. At 0.2 percent of the rats' diet, there were increased mortality and degeneration of the liver. At a level of 01. percent of the substance in the diet, the rats exhibited marked growth retardation. ~~At a level of 0.5 percent, autopsy revealed enlargement of the right side of the heart and slight hypertrophy or hyperplasia of the cells in the liver.~~

Allowed in Par. See Finding 5.

There is nothing in the Record to support the material stricken; material added makes the Proposed Finding more accurate (R. 23-26).*

K. ~~Five milligrams per week given to rats by subcutaneous injection caused increased mortality and moderate~~

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* While, as previously noted, in these exceptions tests are discussed with their results, it should be noted that the Secretary's proposed findings in discussing tests made of Orange 2, states at paragraph b.ii, at the top of Column 2 at p. 9352 of the Federal Register of Dec. 30, 1954, that weekly subcutaneous injections of 0.1 milliliter of a 5 percent suspension of Orange 2 were discontinued after 8 injections because of toxicity. This is erroneous since only 3 of 18 rats were affected (R. 25-26).

~~growth retardation.~~ *In 1953, 18 rats were given weekly subcutaneous injections with 0.1 milliliters of a 5 percent* [fol. 101] *suspension of Orange 2 in glycerine. Control animals were injected with glycerine alone. One of the rats which received the color died following 7 injections. A second died after 8 injections, and the injections were discontinued. A third rat was found dead 11 days after the final injection of Orange 2. There were no deaths among the control animals.* (R. 25-26.)

Denied.

L. ~~Dogs consuming 100 milligrams per kilogram of body weight per day of FD&C Orange No. 2 lost weight or gained poorly. Twenty milligrams per kilogram of body weight per day caused one dog in the experiment to gain weight poorly.~~

For an accurate statement of this finding see Proposed Finding II 1(b) ii., *supra*, p. 5.

Allowed in Part. See Finding 5.

M. Dogs *In 1953 four dogs were started* on a diet containing 0.2 percent of the test substance (*Orange 2*). *They* had diarrhea ~~at the beginning of the experiment~~ *for the first few days on this diet* ~~and exhibited rapid deterioration and weight loss~~. *They ate poorly, lost weight steadily. On the 28th day of the experiment two of the dogs were sacrificed in extremis. They had lost 43 and 32 percent of their initial weight. The remaining two dogs had lost 31 and 21 percent of their initial weight, respectively. They were placed on a normal diet for 9 days, and during this rest period they regained some weight and improved their physical condition. Then with two additional dogs they* [fol. 102] *were placed on a normal diet for 9 days, and during this rest period they regained some weight and improved their physical condition. Then with two additional dogs they were placed on a diet containing 0.04 percent Orange 2. On this diet, the four dogs did well for about a month. Following this they began to eat poorly and lose weight.* ~~At 0.04 percent of the~~ *On this* diet, *the* dogs then gradually deteriorated and lost weight, and autopsy revealed atrophy of various vital organs.

The suggested changes are supported by R. 27-28.

Denied.

N. *In 1952,* a single dose of 200 milligrams *of Orange 2* produced diarrhea in *five* dogs *who had previously been found sensitive to the cathartic action of Orange 1.*

The suggested changes are supported by R. 27-28.

Denied.

O. When *in 1951* FD&C Red No. 32 was fed to rats at a level of 2.0 percent of the diet, all the rats died within a week. At a 1.0 percent level, death occurred within 12 days. *When weanling rats were given 0.5 percent they died within 21 days.* At 0.5 percent ~~most of the~~ *3 of 5 slightly older* rats died within 26 days. At 0.25 percent approximately half of the rats died ~~within 3 months~~ *two rats died in 7 and 6 weeks and the remaining 3 were sacrificed at the end of 10 weeks.* (R. 31-32.)

Denied.

[fol. 103] P. ~~All the rats showed marked growth retardation and anemia.~~ *An experiment in 1952 involved feeding Red 32 in the diet of rats. The results show a marked effect on mortality at a level of .25 percent, a less pronounced effect on mortality at 0.1 percent, and a marked retardation in growth in both groups. Moderate to severe anemia, depending on the dose, and an increase in the white cell count.* (R. 33.)

Denied.

Q. Autopsy revealed moderate to marked liver damage *at the 0.25 percent level of the diet,* ~~Similar but less severe results were obtained with rats on a diet containing 0.1 percent of FD&C Red No. 32. In addition to liver damage, however, autopsy also revealed enlargement of the right side of the heart in this latter group~~ *slight to moderate liver damage and heart lesions at the 0.1 percent level of the diet.* (R. 33.)

Denied.

R. *In 1953,* subcutaneous injection of approximately 10 milligrams per week caused ~~death within 8 weeks to most~~

~~rats on the experiment~~ *per rat resulted in such toxicity that the experiment was discontinued.* These rats exhibited anemia, ~~hemorrhage, and reduction in the size of the liver.~~ *Neither with respect to Orange 2 nor Red 32 was the experimental test continued long enough to reach any conclusion as to the possibility of carcinogenicity by repeated subcutaneous injection of rats.* (R. 34-35.)

Denied.

[fol. 104] S. ~~Dogs taking 100 milligrams per kilogram of body weight per day showed moderate weight loss.~~ See Proposed Finding II 1.(c) i. and ii., *supra*, pp. 6-7.

Allowed in Part. See Findings 7 & 8.

T. ~~A level of 0.2 percent of FD&C Red No. 32 in the diet of dogs caused rapid deterioration and weight loss and sporadic diarrhea; 0.04 percent caused gradual deterioration and weight loss, sporadic diarrhea, moderate atrophy of vital organs, and muscular distrophy; 0.01 percent in the diet caused weight loss and the death of one out of four dogs.~~ In *1953, four dogs were fed a diet containing 0.2 percent of Red 32. Two of these were sacrificed at the end of 26 days after they had lost 28 and 29 percent of their weight. The other two dogs were placed on a control diet for ten days, and after they had regained weight and improved their condition they were placed with two additional dogs on a diet containing 0.01 percent Red 32. One of the four dogs lost approximately 60 percent of its body weight and was found dead after 173 days on the diet. The remaining 3 dogs lost some weight but appeared to be in fair condition after about 10 months on this diet. Four dogs fed 0.04 percent of Red 32 in their diet lost weight up to about 50 percent and were sacrificed in extremis at 124, 137, and 148 days on the experiment. Sporadic diarrhea was observed during the experiment. Pathological examination showed slight or moderate pallor of the organs and tissues in general, gelatinous bone marrow and atrophy of the liver as judged by gross examination. The principal feature shown by the microscopic examination was atrophy and/or cellular depression of the various organs, such as the liver,* [fols. 105-157] *spleen, lymphnodes, bone marrow, genital organs, and skeletal muscle.* (R. 36-37.)

Denied.

U. ~~A single oral dose of 100 milligrams or 200 milligrams gave diarrhea in the majority of the dogs tested.~~ *In 1952, 10 dogs which had previously been found sensitive to the cathartic action of Orange 1 were tested on Red 32. When given 200 milligrams of Red 32, eight of the 10 dogs developed diarrhea. Five dogs were later tested with a dose of 100 milligrams, and four developed diarrhea and one gave questionable results.* (R. 37.)

Coal-Tar Color Industry Committee, By Miachael F. Markel, Attorney.

Denied.

[fol. 158] Before the Department of Health, Education and Welfare Food and Drug Administration

In the Matter of: Color Certification

21 CFR Part 1535

Docket No. FDC-60

EXCEPTIONS FILED ON BEHALF OF FLORIDA AND TEXAS USERS OF FD&C RED #32 IN THE COLORING OF ORANGES

Pursuant to Notice of Proposed Rule Making in the above entitled matter, heretofore published in the Federal Register, under date of December 30, 1954, the users of FD&C Red #32 in the coloring of oranges, who shipped 12,052,522 boxes, or about 88% of the total color-added oranges in Florida in the 1952-53 season, and the users of FD&C Red #32 in Texas, a list of which appears in the [fol. 159] record, and who previously filed a brief in the hearing, excepts to said Order. Some of these exceptions go to the conclusions and some to the facts stated, or not stated, and some to the Order itself.

Exceptions are made to certain findings of fact, the conclusions and the Order as follows:

Exceptions to Findings of Fact No. 2

1. Said finding of fact is erroneous and makes findings that are not warranted or based upon the record of the hearings.

Allowed in Part. See Finding 2.

2. Said finding of fact recites: "A number of these tests with present day technique and procedures have been conducted, and follows with details of the tests." The record does not show, nor does the subsequent recital in Finding of Fact No. 2 show, any difference between the present day technique and procedures and those employed at the time of the original certification of FD&C Red]32. (R. 8-78) (Exhibit 2, 3, 4). (See particularly R. 12-13 as to General Procedure.) (R. 31-32.) Basis of selection of test levels. (R. 42-43.)

Allowed.

3. In Finding of Fact No. 2, Paragraph (c), subsection iv and v, carcinogenicity tests are mentioned, with the implication that FD&C Red #32 produces Carcinoma. This implication is erroneous and is misleading and without foundation. There is no evidence in Exhibit No. 4 of the hearing [fol. 160] or any other place in the record, substantiating even this implication. (Exhibit 4.) (R. 34-35.)

Allowed in Part. See Finding 2.

4. The test recited in findings of fact No. 2 are unrealistic and have no relationship to the method or manner in which FD&C Red #32 is actually used on oranges. The reported data showed no adverse affect when fed at the lowest levels selected for the purpose of testing, and these levels were in excess of the amount of color likely to be ingested under normal conditions of useage. The details of this will be more fully developed in Appendix A, which is attached hereto and made a part hereof the same as if incorporated herein at this point. (Exhibits 2, 3, 4, 8.) (R. 8-78.)

See Findings 8-10.

5. There is error in the finding of fact and the Order based upon the finding of fact insofar as it relates to FD&C Red #32 for the reason that the record affirmatively shows that tests were made upon two ingredients; namely, para-isomer and meta-isomer. (R. 12), and it is not shown that these ingredients were of satisfactory purity as to freedom from poisonous or harmful substances when they were

received or tested. In fact it is not known and it is not shown from the record, that these ingredients were received from a commercial firm ordinarily engaged in preparing FD&C Red #32.

[fol. 161] Exceptions to Finding of Fact No. 3

6. Said finding of facts recites that the tests are the tests normally employed to determine the toxicity of the substance being taken internally by man, but is erroneous in that it does not show the experimental results on any human beings as to the use of FD&C Red #32; the record showing no experiments on human beings except as to Orange No. 1, and this was under an amount vastly in excess of the amounts ingested under normal conditions of use. (R. 44-45.)

Allowed in Part. See Findings 7-10.

6. (a) The finding "the experimental work on man is limited" is erroneous in that it indicates experimental work as to Red No. 32. The record shows no experimental work on man except a small amount on Orange No. 1 (R. 44-45.) This finding should have recited, to have been correct, "there is no evidence that in the amounts used and in the manner of use in the coloring of citrus fruit, the product so colored is not safe for human consumption".

See Findings 8-10.

7. The finding of fact is erroneous in that it recites that pharmacological tests conducted by qualified investigators using recognized scientific methods estabished that the colors are not harmless substances.

These findings are erroneous in that it did not take into consideration the uses to which it is put, and the amount which would be ingested under normal conditions of use, the record showing that in the ratio of the amounts fed to the rats and dogs and fed to human beings, it is not harmful to human beings and is not harmful to human beings [fol. 162] in the manner and quantities in which it is used, and the finding should have so recited. (Exhibits 4, 8.) (R. 8-78.)

See Findings 8-10.

The witness, Doctor Vos, on cross-examination, (R. 43-44-45), admitted there had been not a single complaint against FD&C Red #32.

8. The findings in the last paragraph of Finding of Fact No. 3 is erroneous and unsupported by the evidence insofar as it refers to Red #32; the evidence showing that FD&C Red #32 is used exclusively for the coloring of oranges on the outer rind of the orange in infinitesimal amounts (4 ppm) and the tests were not made with reference to the manner of the use or based on the quantities of use to which Red #32 was put. (Exhibit 4, 8.) (R. 42-43.) (R. 101.)

Denied. See Findings 7-10.

Exceptions to the Conclusions and to the Tentative Order as a Whole, insofar as it Relates to FD&C Red #32.

9. The conclusion is erroneous in law and fact in stating that:

Based upon the evidence of toxicity presented at the hearing . . . FD&C Red #32 is not harmless and suitable for use—in coloring food.

Denied. See Findings 7-10. Conclusions 1-4.

This is erroneous in that an erroneous construction has been placed upon the words "harmless and suitable for [fol. 163] use in coloring foods". There is no evidence that FD&C Red #32 is not harmless and suitable for use in the coloring of oranges. None of the amounts used in the tests, including the lowest levels of feedings which produced no injury, bear any relation to the use of these colors likely to be ingested under normal conditions of use. (R. 42-43.)

Exceptions to the Tentative Order as a Whole insofar as it Relates to FD&C Red #32.

10. The finding is based upon tests of materials unidentified as to purity, or place of acquisition, as shown in Exception No. 5.

Denied. See R. 86-88.

11. The record provides no factual basis for an Order amending the coal-tar regulations, so as to delete therefrom FD&C Red #32. (R. 8-78.) (Exhibits 4, 8.)

Denied.

12. The record affirmatively establishes FD&C Red #32 to be harmless and suitable for use in the coloring of oranges, and yet the Order is contrary to this, and is erroneous. (R. 8-78.) (Exhibits 4, 8.)

Denied.

13. The same exceptions as made to the conclusions are made to the tentative Order as a whole. In addition, the finding and determination of the word "harmless" is contrary to the long-established recognition of this word by the Food and Drug Administration and contrary to the [fol. 164] legislative history of the Act. There is no showing in the record of any complaint of the use of FD&C Red #32, or that it is harmful, either in law or in fact.

14. The interpretation now attempted to be placed, and the provision "Be deleted from listing", changes the long recognized interpretation of the word "Harmless" and the original certification made after complete evidence. FD&C Red #32 was certified nearly a quarter of a century ago. No adverse affects have been reported to the Department; and the Order is based upon proposed findings that are incomplete, and fail anywhere in the findings to show particularly that FD&C Red #32 is only being used for the coloring of oranges certified upon the original complete hearing of the Department, found to be harmless and was in common useage prior to the original certification.

Denied.

15. The Order is predicated on an erroneous belief that the Department had to enforce zero-toxicity and could not consider or establish any tolerances or consider the manner in which the dye is used.

Denied.

Respectfully submitted, (S.) J. Hardin Peterson, Attorney at Law, Attorney for Users of FD & C Red #32 Named in detail in the original brief filed in this matter.

Lakeland, Florida.

[fol. 165] APPENDIX A TO EXCEPTIONS

Dr. Vos Toxicity Tests on FD&C Red #32—Exhibit 4.

Color-added oranges were analyzed by the Food and Drug Administration and also by the Florida Citrus Commission independent of each other and on entirely separate samples of fruit. Both reported 4 parts per million of Red #32, contained on the basis of the total weight of the fruit. (R. 101.)

Dr. Vos' Reported Experiments:

Experiment #1. Begun in 1940.

Rats fed 0.1 Red #32 in diet showed markedly depressed growth and reduced median survival.

0.1% corresponds to 1000 ppm (parts per million) which is 250 times that found in oranges (of which the peel is not eaten). This is 2.5 times the "100-fold margin of safety" published by Dr. Lehman.

Experiment No. 2. Begun in 1941.

0[illegible]% of Red #32 in diet of rats.

Again 250 times that found in oranges.

Experiment #3. Begun in 1951.

a. Rats fed at 2% level of Red #32 in diet

b. Rats fed at 1% level of Red #32 in diet.

c. Rats fed at 0.5% level of Red #32 in diet.

[fol. 166] This corresponds to:

a. 20,000 ppm or 5,000 times the amount found in oranges.

c. 5,000 ppm or 1250 times that in oranges.

b. 10,000 ppm or 2500 times that in oranges.

Experiment #4. Begun in 1952.

a. 0.10 Red #32 fed in diets of rats.

This is 1000 ppm or 250 times that in oranges.

b. 0.25% Red #32 fed in diet of rats.

This is 2500 ppm or 625 times that in oranges.

Experiment #5. Begun in 1953.

Rats injected with Red #32 periodical in tests for carcinogenicity.

No evidence of car-inoma found per Vos' report.

Experiment #6.

Same as Number 5, but again per Vos' report—no carcinoma found.

Experiment #7. Begun in 1938.

5 dogs fed milligrams of Red #32 per kilogram of body weight per day (mf/kg per day) for a period of 5 to 6 years.

One dog received 100 mg/kg per day for one month and later 20 mg/kg per day for one month.

[fol. 167] Another dog received 100 mg/kg per day for 10 months and then 20 mg/kg per day for the balance of 5 years.

The conclusion of this experiment as reported was "Pathological examination of the animals following sacrifice showed no changes which could be attributed to treatment".

An average dog weighs about 10 kilograms (kg) and eats about 400 grams (about 1 pound) of food per day. Calculations in term of parts per million are as follows:

a. 5 mg/kg/day is equal to 125 parts per million.
b. 20 mg/kg/day is equal to 500 parts per million.
c. 100 mg/kgday is equal to 2500 parts per million.

These values re respectively 31; 125; and 625 times the amount of dye found in oranges.

Experiment #8. Begun in 1953.

a. Dogs fed 0.2% Red #32 in diet.
b. Dogs fed 0.04% Red #32 in diet.
c. Dogs fed 0.01% Red #32 in diet.

These levels correspond to respective levels of 2000 ppm, 400 ppm, and 100 ppm, or 500; 100; and 25 times the amount of dye found in oranges.

Experiment #9. Begun in 1952.

Ten dogs were fed on empty stomachs 200 mg of #32, in capsules, but with no food, and therefore no dilation whatsoever.

[fol. 168] Mathematically, this is infinity times the 4 ppm found in oranges. It would seem that this test is meaningless.

However, 4 ppm of dye in an orange, amounts to 0.8 mg per orange. Since an average man weighs about 7 times the weight of a dog by comparison, a man would have to be

given (on an empty stomach) 1400 mg of dye. Thus to get this amount by eating oranges, a man would have to eat 1700 oranges at one time and—peel and all.

Before Department of Health, Education, and Welfare
Food and Drug Administration.

Notice of Proposed Rule Making Color Certification.

BRIEF OF INTERESTED USERS OF FD&C RED #32 AND OTHERS REFERRED TO IN THE BRIEF IN SUPPORT OF EXCEPTIONS TO TENTATIVE ORDER DATED DECEMBER 22, 1954.

This brief is filed on behalf of Florida and Texas packers and packing houses using a coal-tar color FD&C Red #32 in the coloring of oranges, and are the same parties as appeared and filed a brief by Michael Markel and J. Hardin Peterson, and all are users of this coloring method and many of these are citrus growers, and as growers, are members of the Florid- Citrus Mutual, which filed an appearance in the said matter, and are under the regulations of the Florida Citrus Commission, which also filed an appearance in the said matter and are interested parties who will be adversely affected by the tentative Order; the names of the interested parties being shown on the last page of the brief.

[fol. 169] Exceptions Nos. 1 and 2 to Finding of Fact No. 2.

In view of the fact that this brief is attached to the exceptions, for convenience we are not repeating the exceptions verbatim.

These findings are based upon the general statement that there had been an advance in knowledge and technique in the field of pharmacology and that a number of these tests, with present-day's technique and procedures have been conducted. The details of the tests are set forth and appear on pages 8 to 78, both inclusive of the record, and Exhibits Nos. 2, 3 and 4.

The findings are in error and based upon an erroneous assumption. There is nothing in the record to show advance in knowledge and technique or new technique and procedure. No references in the hearings at any place are made to advance in knowledge and technique, or to new methods; to the contrary, a comparison of the methods used in this hearing, and the tests which served as a basis

for the acceptance of the original list of 18 food colors shows that the same methods of tests were used.

The pharmacological tests that served as a basis for acceptance of the original list of 18 food colors are described in a paper entitled "Coal-Tar Colors: Their use in foods, drugs and cosmetics" by Dr. Herbert O. Calvery, former Chief of the Division of Pharmacology, Food and Drug Administration. This paper appeared in the American Journal of Pharmacy, Vol. 114, No. 9, pp. 324-349, September 1942. The following three paragraphs are of interest:

[fol. 170] "Fortunately our pharmacological investigations of the fifteen colors on the certified food list and several others, some of which we had had under way for a period of over two years, had been sufficiently extensive to furnish us a basis of evaluation of the new colors. These investigations, using different species of animals, had included: acute tests by oral and intraperitoneal administration; sub-acute feeding experiments incorporating low, medium, and high levels of the dyes in the diets (in some of these experiments the animals were permitted free access to food while in others the "paired feeding" technique was used) and chronic feeding experiments with different levels of the dyes in the diets."

"In light of the early experience with Sudan I and Butter Yellow and in view of other considerations, it was immediately obvious that no new color, however essential it seemed to be, should be added to the list, even with a background of commercial use, until a variety of pharmacological data were available to show its relative toxicity and its harmlessness and suitability for use when compared with the well-known food colors."

"Our investigations consisted of the determination of the acute oral toxicity on rats, the acute intraperitoneal toxicity on mice, and a minimum of sixty days subacute feeding experiments. In these experiments three levels of the dye were fed to different groups of rats, the highest level being sufficiently large in all cases to produce positive results. In addition we tested each of the colors for their effect on the skin of groups of guinea pigs by the technique Landsteiner and his co-workers used in their investigations [fol. 171] of the ability of compounds to cause skin sensi-

tization. They had found that the skin of the guinea pig responds to most chemical compounds in a very similar manner to that noted in man."

There is nothing new between these tests recited and the tests recited in the tentative Order.

Exception No. 3.

This exception is based largely on the wording and the fact that it, by inference, may have indicated carcinoma. If mentioned at all, it should have been followed with the finding that there was no showing of carcinoma. The evidence definitely shows this. (Exhibit #4.)

Exception No. 4.

We are including in Appendix A, a complete analysis of the method by which the feeding tests were made. These will show they are totally unrealistic and have no relationship to the level or manner in which FD&C Red #32 is actually used on oranges. These tests show that the doses given were given under far different conditions than would have ever been used normally, and that the amount necessary to be taken into a human being would be so great that under no possibility would a human being ever get that amount of the dye.

Exhibit No. 4 shows the nature of the experiments. The testimony shows the high levels at which the tests are made. Using ordinary well known data and reducing the [fol. 172] amount in preparation to the use by humans, we submit a detailed analysis which we attached as Supplemental Sheet A-1 and make it a part of this brief the same as if included herein.

There was a total absence of effort to relate tests to ordinary use level. This is borne out by the testimony of Doctor Vos on page 43 of the record, (R. 43) in which the following questions and answers occur:

"Q. Well then, these levels were not specifically related to the levels of these colors as actually used under normal conditions of use?

A. No, that was not a part of this.

Q. Have you any evidence at such levels where the

capacity for producing harmful effects was tested at levels of ordinary conditions of use?

A. I have very little information on the matter of what the customary levels of use are".

And there is lack of evidence of harmful effects at the levels of ordinary use.

Doctor Vos again on pages 44 and 45 of the record, testified as follows: (R. 44-45):

Question: Dr. Vos, then you have no evidence as to the capability of producing harmful effects of any of these colors at the level of ordinary use under normal conditions of use, I should say.

Dr. Vos: Without having more thorough information on the actual level of ordinary use, I would hesitate to answer that question.

Question: Well, you have no evidence at levels other than the levels appearing in the exhibits.

[fol. 173] Dr. Vos: That appear in the exhibits, that is correct."

Also see page 42 and page 43 of the record. (R. 42-43) with reference to basis for selection of test levels.

Exception No. 5.

There is no Showing of the Purity of the Ingredients Tested. We respectfully feel that there is such an important question on this one phase, that new tests should be made entirely on FD&C Red #32.

Doctor Vos testified (R. 11-12 as follows):

"Q. Has the Division of Pharmacology also carried out experimental work on FD&C Red 32?

A. That is correct.

Q. What was the source of the color used in these experiments?

A. All of that color was obtained from the same source as the preceding two, with the exception of two ingredients known as para-isomer and meta-isomer. These were obtained directly from a commercial firm.

Q. Is that a commercial firm ordinarily engaged in preparing FD&C Red 32 for use in foods, drugs and cosmetics?

A. I don't know".

The record does not show what source the two ingredients were obtained; does not show that the components had a satisfactory purity as to freedom from poisonous or harmful substances; that the witness didn't know whether they were received even from a commercial firm that was ordinarily engaged in preparing FD&C Red #32 for use. [fol. 174] Certainly when tests are made, it is important that the ingredients used in the tests should be free of poisonous or harmful substances and should be of known purity; the source from which they came should be definitely established; even the containers in which they are received and in which the tests are made are important in arriving at a fair test and to seek to withhold from an industry the use of a dye previously found to be harmless by the Food and Drug Administration after extensive tests and base this withholding upon analysis made of ingredients from which we do not know and the record does not disclose and the witness himself didn't know, is a most serious matter, and we respectfully submit that we feel this one thing in itself is important enough to cause the entire matter to be referred back for further study as to FD&C Red #32, and to have the Honorable Secretary withhold her approval of the final Order.

Exceptions as to Finding of Fact No. 3.

The finding recites that the tests that have been concluded are the tests normally employed to determine the toxicity of substances taken internally by man, and that pharmacological tests conducted by qualified investigators using recognized scientific methods established that the colors are not harmless substances.

Examination of the record will show that there is no evidence to the effect that FD&C Red #32 is harmful to human beings. In fact the record does not show any tests made on human beings of FD&C Red #32. The record shows clearly that the only tests made on any human beings was with reference to FD&C Orange #1. (R. 20-21.)

[fol. 175] The record (R. 128-129) shows that the sale of FD&C Red #32 has been discontinued for any other purpose than the coloring of oranges.

Doctor MacDowell, in his testimony (R. 1.01) and Exhibit 8, shows that juice extracted from color added oranges contained from .04 to .07 ppm (parts per million) of dye. This shows clearly and the analysis attached as A-1 shows the absurdity of claiming that it is harmful to man. Such being the case, its use in the coloring of oranges should not be prohibited.

As late as in 1950 the Food and Drug Administration, in the matter of Violet No. 1, did not apply a strict definition of "harmless" or say that it was harmless. They said:

"The amount of color fed to animals in the tests referred to in Finding No. 12 was far in excess of the amount that any human might obtain as a result of food colored with FD&C Violet #1."

(Finding of Fact No. 12. Federal Register, Vol. 15, No. 109, Page 3517, June 7, 1950.)

The witness, Doctor Vos, stated on page 63 of the record (R. 63):

"The Witness: *I think it is appropriate the method of use should be taken into consideration.* The dyes in question are at present being certified for use in foods, drugs, and cosmetics, and the data which we presented in these exhibits have shown that they are not harmless for use in *all* of those products. As I have pointed out, we have no [fol. 176] date as to whether they are or are not harmless for external application." (Italics ours.)

And on Page 62 of the record, the witness, Doctor Vos said:

"Yes, the amount of dye, of the color has to be considered in determining whether or not it is harmless."

And on Page 57 (R. 57), Doctor Vos also said:

"Q. Dr. Vos, aren't the amount and method of proposed use of material necessary data for deciding whether the material is harmless for the use intended?

"A. May I hear that question again, please?

(Question read.)

The Witness: I would say yes."

Exceptions to Conclusion and to the Tentative Order as a Whole

Exception to Nos. 9 to 15 Both Inclusive

Exception No. 10 is to the general Order and has been previously argued. We take the position that the tests of FD&C Red #32 were not correct. It is not shown clearly the source of material, nor whether it was of sufficient purity to be tested. If the test is erroneous, the Conclusion and the Order itself would be erroneous.

[fol. 177] The Conclusion and Order being based upon the alleged evidence of toxicity and the finding that FD&C Red #32 is not harmful and suitable for use in coloring of food will be argued together, for convenience.

From reading the record and reading the tentative Order, we feel that the Conclusions and the Order are based upon an erroneous assumption and construction of the word "harmless". This construction attempted in this Order is different from that which has been used by the Food and Drug Administration for many years. It is different from the Congressional intent. In the previous brief we quoted rather extensively from the legislative history. It was never intended by Congress to have the word "harmless" construed as zero-toxicity.

It is interesting to note that the testimony on the safe-y of use at the 1939 hearings was presen-ed by Doctor Herbert O. Calvery, a former Chief of the Division of Pharmacology, F. D. A. Doctor Calvery related how he had conducted both acute and long term studies and had administered the products by mouth, by skin contact and by intraperitoneal injection, and using at least three species. He testified:

"We have been engaged in our laboratory for a period of approximately three years in the study of the toxicology of dyes".

(USDA FD&C #4 February 7, 1939. Page 228.)

Among other things he said:

"On p. 233 there is an interesting passage.

Q. "Are there in your opinion any coal tar colors that are harmless and suitable for use in all kinds and classes of Foods, Drugs and Cosmetics."

[fol. 178] A. (Dr. Calvery). "No, in my opinion there are no coal tar colors that are harmless and suitable for use in all kinds and classes of Foods, Drugs and Cosmetics." ...

On p. 243 he states: "Fifteen colors formerly used and certified as food colors. They have been in use for a number of years, and so far as we are aware there is no harm that has come from their use.

"Again on page 243:

Q. "What do you mean by the terms that you have used, harmless and suitable for use? The use to which the color is to be subjected?"

A. "Yes, by harmless and suitable for use for purposes indicated, we mean that in the concentrations that these substances are used for coloring purposes, it is our opinion that no harm can come from them to the user when used in the concentrations for which they are designed and for the purposes for which they are designed" ...

"Q. In considering the amount used, does the tinctorial property of these coal tar colors have some bearing on the amount used?

"A. "Yes, the tinctorial properties of the coal tar colors is such that when they are used in foods, drugs and cosmetics they are used in relatively small percentages, and one takes that into consideration when one speaks of the toxicity of these substances assumed as harmless and suitable for use in drugs and cosmetics." ...

"Q. "Dr. Calvery, how do you arrive at percentage of color which should be allowed as harmless and suitable for use in foods, drugs and cosmetics?"

[fol. 179] "A. "We arrived at the conclusion that we have concerning the use of these from our conferences with the cosmetics, food and drug manufacturers, and after learning from them what the percentages are which in most cases are a fraction of a per cent, we based our reasoning on that premise. The colors are not certified for use as colors to be consumed as colors. They are certified—at

least we are permitting the listing of these for certification —on the basis of the fact that they will be used as we have been told they are being used at the present time, that is, in small percentages.'' . . .

''Q. ''Now, have you reached an opinion as to the maximum percentages of coal tar colors which would be allowable respectively in foods, drugs and cosmetics, in view of the tolerances for impurities which have been established in these present regulations?''

A. No, we haven't reached a definite conclusion as to what is the maximum that may be permitted. It is our understanding as I pointed out before that these colors are used in relatively small amounts, in most cases only a fraction of a per cent in the finished product. . . .

—if manufacturing processes and the use of these colors should change to such an extent that more than these amounts should be used, on which we have actually taken into consideration in considering the toxicity of these colors, if that should change to an extent whereby larger amounts would be used, I think there would be no question but that we would have to take that into consideration in order of time and consider amendments to the present regulation.''

In an article by Doctor Herbert O. Calvery, which is headed: ''Coal-tar colors—their use in Food, Drugs and [fol. 180] Cosmetics, by Herbert O. Calvery, Division of Pharmacology, Food and Drug Administration, Washington, D. C. September 1942, Page 326, Amer. Journ. Pharm., the reference is used:

''Used in foods were harmless in the quantities employed.''

And, in another place the words: ''Free from harmful constituents.''

And, on Page 329, the words: ''Which might render such foods injurious to health''.

It includes on Page 330, etc. ''The selection and rejection of coal-tar colors Under the Act of 1906''.

On Page 334, he states: ''Fortunately our pharmacological investigation of the fifteen colors on the certified food list . . . had been sufficiently extensive to furnish us a basis of evaluation of the new colors . . .''

He gives somewhat in detail the type of experiments which bears out what we have heretofore said, that the

technique used then are the same as used today, and on Page 337 he makes the statement, which we feel is correct, that the Department has certain discretion, has the right to fix tolerances and to consider the methods under which it is used. He used these words, in referring to the Act of 1906, and to the Act of 1938:

"The development of the system of certification for coal-tar colors was a precedent that laid the ground-[fol. 181] work for other and more effective control measures . . . It was the forerunner of the present system of certification of coal-tar colors; under it were set the first tolerances for heavy metals . . ."

What is said above is borne out also by Doctor Campbell in the hearings on the Food and Drug Act in the 1935 hearings. (Senate Hearings S5 Page 59.) That zero-toxicity could not be expected was recogized by Doctor Campbell. He stated:

"There are very few things, as an illustration, in which you will not find contaminating products in some small degree. With our industrial development, it is *extremely difficult to acquire absolute purity in the production of our food supply.* (Italics ours.)

And on Page 60 of the same hearings, he said:

"Now, under the terms of the present law and under the terms of this measure as I have read it so far, action would be authorized in such cases only when the amount of that added deleterious ingredient was sufficient to injure health. There is a complete exclusion of added deleterious ingredients by this section, except where necessary in the production of the product or where unavoidable. In those instances the poison will be permitted or tolerated in amounts corresponding to the need of using the poison, or its unavoidability, in each particular food. The total of the amounts so allocated will not be enough to jeopardize health . . ."

Thus it will be seen that a practical definition of the word "harmless" should be used; that the Congress itself [fol. 182] knew that the colors could not be 100% pure; those administering the Act and sponsoring the Act knew this.

Subparagraph (b) of Paragraph 346 USCA Title 21, by its subheading indicates that those grouping it reached the same conclusion because the subheading is:

"346. Tolerances for Poisonous ingredients in Food and Certification of coal-tar colors for food. Regulations for Tolerating Unavoidable Poisonous Ingredients".

Senator Copeland, who was Chairman of the Committee on Commerce when the hearing was being held in 1935, recognized this also. When reference was being made to spell out tolerances regarding certain ingredients in cosmetics, Senator Copeland said: (Senate hearings 35 Page 39.)

"Senator Copeland: Well, of course, that is covered by the general term that it should be deemd to be adulterated if it bears or contains any poisonous or deleterious substance which may render it injurious to health. So the Department itself would have to determine whether there was too much of this or that poison in the cosmetic, if there is any there".

The fact that the Food and Drug had discretion in coal-tar matters is also borne out in pages 318 and 319 of the hearings in a colloquy between Senator Copeland and Doctor Harrison and the words "Harmful to health" are used. On page 318 Senator Copeland said:

[fol. 183] "Senator Copeland: Is back of this the thought that these coal-tar colors might be harmful to health?"

"Doctor Harrison: I think there is back of this original phrase the thought that coal-tar colors might be harmful to health".

And then when the question came out to clarify it, it is pointed out, page 319, that the "certification would be in accordance with regulations".

Certain phrases of the interpretation of the word "harmless" as shown by the legislative history and legal decisions thereon will be shown later in this brief.

The Record Provides no Factual Basis for an Order Amending the Coal-Tar Regulations so as to Delete Therefrom FD&C Red #32

Section 135-3 listing "straight colors" for certification for use in food includes FD&C Red #32. The deleting

of FD&C Red #32 would deny the further use of this color for the purpose of coloring citrus fruits.

The sole record basis in support of the proposal, as stated, is the testimony of Dr. Dert J. Vos (R. pp. 8-78, inc.). This testimony includes a report of ten pharmacological studies carried out by feeding Red 32 to the number and kind of animals as appears in detail in this testimony and in Exhibit 4. There is no need, for present purposes, to analyze each of the experiments reported. This becomes particularly unnecessary since Dr. Vos has stated, on the one hand, that the levels fed to the test animals, in conducting the experiments which he reported, bore no relation whatever to the level of the dye likely [fol. 184] to be ingested by humans under oridinary conditions of use (R. p. 43), and that he had no evidence of the capability of the color to produce harmful effects at levels likely to be ingested under ordinary conditions of use (R. pp. 44-45), and, on the other hand, that the amount of the dye and conditions under which it is used are essential factors in determining whether or not it is harmless (R. pp. 57-8, 62).

The witness concluded his direct testimony by stating that it was his opinion that Red 32 "is not a harmless coal-tar color", without explaining how he arrived at that conclusion (R. p. 38). However, later the witness defines his term "harmless" by saying: "I have said that these colors are not harmless in the sense that they did cause harm to the experimental animals in the experiments which are listed here". (R. p. 67.) Thus it becomes apparent that he arrives at his conclusion of "not hamless" by ignoring his own criteria for establishing harmlessness, namely, the level likely to be ingested under normal conditions of use. This conclusion also ignores the basis for determining harmlessness by the witnesses and by the then Secretary's findings when Red 32 was originally placed on the list in Section 135.03, as being "harmless and suitable for use in food." (F.D.C. Docket No. 9; see particularly Findings 21, 22, and 25 of Order dated May 4, 1939, Federal Register for May 9, 1939, p. 1924.) There is no evidence in the record now before the Secretary which overcomes the evidence and considerations

on the basis of which Red #32 was thus listed for certification.

The only other basis for the conclusion of "not harmless" of Red #32, as stated by the witness, is his state-
[fol. 185] ment that, in determining harmlessness of a substance, its potentiality for producing harmful effects should be compared to such potentiality of substances known to be poisonous and generally regarded as such. When pressed for such a comparison, carbolic acid was selected as such a substance (R. pp. 49-51). On more detailed questioning as to the soundness of this comparison the witness admitted that carbolic acid was considered to be a poison—"not harmless"—on the basis of its acute oral toxicity, or LD 50, and its effect on the skin (R. p. 73). However, the witness also admitted on the basis of his own knowledge that the acute oral toxicity of Red 32 was "much less" than that of carbolic acid and that Red #32 had no adverse effects on the skin (R. p. 77). Obviously, this comparison, if sound, then affirmatively established Red #32 as not being a poisonous substance, hence safe or "harmless"; if, on the other hand, the comparison is unsound (from the witness' standpoint the more charitable view), then it still fails to furnish a basis for the stated conclusion, since the record contains no other evidence of the acute oral toxicity and potentiality for harmful effects of known poisons.

It is submitted, therefore, that the record, and particularly the considerations by the witness on the basis which he expressed his conclusions of "not harmless", as summarized, fails to establish a legal basis for amending the coal-tar color regulations as proposed, since the witness' own criteria for establishing this ultimate fact fail to support his conclusion and since Section 406 (b) does not contemplate a determination of the fact of harmlessness on the basis of any of the criteria relied upon by the witness.

[fol. 186] Section 406 (b) is mandatory in its provision. It provides that the Secretary "Shall promulgate regulations providing for the listing of coal-tar colors which are harmless and suitable for use in food, and for certification of batches of such colors." This language contemplates a determination of harmlessness and suitability under normal conditions of use, including the quantity of a

substance which is likely to be ingested under such conditions. The regulations now sought to be amended were obviously established and promulgated on the basis of such a concept. Nothing has happened since then nor does the record contain any evidence suggesting otherwise.

The suggested basis for determining harmlessness also squares with the concepts generally accepted by experts. When pharmacologists and toxicologists approach a question as to whether the substance is harmless or not, the very first question they wish answered is the proposed level of use and the extent of use. Such questions can only imply that harmlessness and suitability of food ingredients, including coal-tar colors, can be determined only when related to specific conditions, including manner and quantity of use. They do not approach the determination of this question by considering all possible abuses which might cause some injury under some conditions of abuse. Dr. Vos' testimony on cross-examination supports these general statements of accepted scientific concepts in evaluating harmlessness of substances intended for food uses.

Intent of the Word Harmless

The succeeding discussion dealing with the Legislative history will show that the word "harmless" should be con- [fol. 187] strued in connection with the entire Act. I am not unmindful of the fact that certain of the provisions of the food, drug and cosmetic Act specifically provide for tolerances, and while no specific rule is spelled out for tolerances in sub-section (b) of Paragraph 346 U. S. Code Annotated, the Secretary is authorized to promulgate regulations, and the whole purpose of the act seems to be that when good manufacturing practices cannot avoid there being some poison, the test is "as he finds necessary for the protection of public health". Tolerances are allowed for residuals in apples, peaches, cherries and other fruit on which it is known that the outside peeling or rind will be eaten, and in some instances must be eaten. Certainly we cannot assume that Congress, which specifically recognized the coloring of oranges, should expect less consideration for a color that is placed outside on the rind when the rind is not eaten and only in extreme instances an infinitesimal amount might get into the juice or in the marmalade, so its

undoubted purpose was to consider the use of the word "harmless" in the manner in which the particular coloring matter is used.

A discussion of the general rules of statutory construction is set forth at 410 and 411 of 50 American Jurisprudence with the supporting cases, and the following are some of the rules which are well supported.

"It is clear that words may not be given a distorted or strained meaning to satisfy the demands of a strict construction."

"A construction which would render the subject to the rule of strict construction is nevertheless entitled to a reasonable, sensible, and fair construction".

[fol. 188] "A construction which would render the statute absurd or unreasonable, is also to be avoided".

"A statute which is subject to the rule of strict construction is nevertheless entitled to a reasonable, sensible, and fair construction".

"The Courts should take a common sense view of the statute as a whole."

"Captious objections, and even the demands of exact grammatical propriety, should be disregarded". (30 American Jurisprudence Pages 410 and 411.)

"The construction must be reasonable. It is a well recognized principle that the law is not concerned with trifles. The doctrine of de minimis non curat lex is well recognized." (See United States V. Hocking Valley Ky. Co., 194 Fed. 234, N.D. (1911) On the subject of de minimis see also Bristol-Meyers Co. v. Lit Bros., 536 Pa. 81, 6 A. 2d 843 (1949); National Labor Relations Board v. Bowell Portland Cement Co., 106 F. 2d 198, C.C.A. 9th (1939); and Willson v. Kable, 177 Va 668, 15 S.E. 2d 56 (1941)" (p. 16, Note 33).

In the various cases that have gone to the Courts of Appeals and to the Supreme Court we find the use again and again of words

"Injurious to health"

"Endanger health"

"Deleterious"

[fol. 189] "Not deleterious to health"

"To safeguard the public health"

Not one has ever contended that the use of the coal-tar colors which are now being studied, have ever been injurious to a human being or will become injurious in the normal use to which it is put in the coloring of oranges. It cannot injure the health of an individual and it will not cause ill effects in the manner in which it is used.

Some of those cases were under the old 1906 Food and Drug Act, but the general principles still apply.

In the Lexington *ton* Mill and Elevator case, 202 Federal at page 615 in which the Circuit Court of Appeals reversed the District Judge, the opinion of the Court, among other things, said:

"The trial Judge decided that if the added substance was qualitatively poisonous, although in fact added in such minute quantity as to be non-injurious to health, it still fell under the ban of the statute, . . . There is no warrant in the statute for such strained construction. The object of the law was evidently:

(1) To assure to the purchaser that the article was what it purported to be and

(2) To safeguard the public health by prohibiting the inclusion of any foreign ingredients deleterious to health."

(Citing Hall-Baker Grain Company vs. U.S. 198 Fed. 614.)

[fol. 190] Page 621 of the opinion is very enlightening and it shows the fact that poisons in some greater amounts are frequently present in potable water, bacon, ham, fruits, and certain vegetables, etc. It refers also to "the deleterious effect intended to be prevented by the act".

This case went to the Supreme Court of the United States and in the opinion the Court upheld the decision of the Circuit Court of Appeals, and among other things, said:

"It is evident from the charge given and request refused that the trial Court regarded the addition to the flour of any poisonous ingredient as an offense within this statute, no matter how small the quantity and whether the flour might or might not injure the health of the consumer. At least such is the purport of the part of the charge above given and if not correct it was clearly misleading, notwith-

standing other parts of the charge seemed to recognize that in order to prove adulteration it is necessary to show that the flour would be injurious to health. . . If it cannot by any possibility where the facts are reasonable considered injurious to the health of any consumer, such flour, though having a small addition of poisonous or delerterious ingredient may not be condemned under the act. . ."

The evidence in the case does not present a disputed issue of fact, but rather a difference between chemists over the meaning of the words "deleterious ingredient, injurious to health"—In recognizing that a small quantity of arsenic is not injurious to health, the government acknowledges that this term is a relative one. Arsenic is found in [fol. 191] infinitesimal quantities in so many articles of feed that it has been said that the air we breathe, the water we drink, the smoke and dust we inhale, and all the foods we consume contain arsenic. If the terms be an absolute one, then they would all be condemned. The quantity of arsenic found in this coloring material is so infinitesimal that, when diluted as it is ordinarily used, it would take years to produce 'a dose' such as is ordinarily prescribed by physicians—one-thirtieth of a grain. In other words, one would be required to drink 150,000 bottles of soda before he would have consumed a quantity of arsenic sufficient to equal the 'dose'.

It may be true that by further process the amount of this drug can be reduced, but complete elimination is impossible. The Congress has not assumed to define with absolute particularity what is or what is not injurious, and we cannot accept the testimony of the one witness who testified for the government to the effect that the word 'injurious' is an absolute term. Rather do we conclude upon the testimony before us that the arsenic present in the quantity disclosed was not injurious".

In this case also the Court stated the purpose of the Act was:

"The purpose was (1) to protect purchasers from injurious deceits by the sale of inferiors for superior articles, and (2) and to protect the health of the people from the sale of normally wholesome article to which have been

added substances poisonous or detrimental to health" (C.A. 7th Circuit, 286 Fed. Rep. Page 84.)

[fol. 192] In the case of United States v. 1950 boxes of Macaroni, although this was an actual adulteration case and it was shown that the addition was poisonous, the Court pointed out:

"It is the duty of the Court to give a fair and reasonable construction of the accomplishment of its object, that object is the exclusion from Interstate Commerce of Fruit products so adulterated as to endanger health" (U.S. vs. 1950 Boxes of Macaroni, 181 Fed. 427.)

At other places in the opinion the Court uses the following words:

"As to the term poisonous", let me state that everything that contains poison is not poisonous. It depends upon the quantity and the combination. A very large majority of the things consumed by the human family contain, under analysis, some kind of poison, but it depends upon the combination, the chemical relation which it bears to the body in which it exists as to whether or not it is dangerous to take into the human system".

This case also sets forth the purpose to protect the public health from possible injury by adding to articles for food consumption, poisonous or deleterious matters which might render such articles injurious to the health of consumers. (Lexington Mill and Elevator Co., 232 U.S. 399; 58 Law/Ed. 658.)

It is interesting to note that the Circuit Court of Appeals pointed out the significance of the fact that no injurious effect had ever been observed. In our case none has ever [fol. 193] been observed. No one claims it will occur to a human being under normal usage. The Circuit Court of Appeals in its opinion in the Lexington Mill and Elevator case, 202 Federal Reporter, 615, just cited, cited the case of W. B. Wood Manufacturing Company v. United States (see C.A. 7th Circuit, 286 Federal Reporter, p. 84, which was a coloring case under the old Act which prohibited the addition "of any poisonous or other deleterious in-

gredient which may render such article injurious to health".

In this case it was definitely established there was arsenic in the color, but notwithstanding this, the Court said:

"(2) We are not satisfied, however, that arsenic in such quantity as to be injurious to health was present. The government recognized the impossibility of eliminating arsenic entirely. In fact, the testimony shows that the elimination of arsenic would be at most but a matter of degree. The government certifies color when arsenic is present, and when only slightly less than that found in the confiscated product.

In the case of United States vs. Washington Dehydrated Food Co., 89 Federal Reporter 2d Series, 606 (Circuit Court of Appeals 8th Circuit) which case dealt with apple chops which had been made of apples that had been sprayed with arsenic of lead and a small residue of the spraying compound had remained on the apples after washing and had been carried over into the apple shops, the Court said this:

"The Government's experts were of the opinion that even infinitesmal amounts of these poisons contained in [fol. 194] food might, if a food was regglarly eaten during a considerable period of time, produce in some consumers chronic lead or arsenic poisoning, while the claimant's experts were not in accord, and expressed the belief that lead and arsenic were largely insoluble and in the gastric juices, etc". . .

The Court further in the opinion said:

"It is noted in this connection that no expert who testified upon the trial was able to say that he knew of any case of lead or arsenic poisoning resulting from eating apples which had been sprayed with arsenic of lead, or the products of such apples."

The District Court below rendered Judgment for the claimant and the Circuit Court affirmed his judgment and held there was no such adulteration as contemplated by the statute.

In the case of French Silver Dragee Co. v. United States, 179 Federal 824, the Court pointed out that the act uses such words as "false," "misleading", "deceit," "poisonous", "deleterious" and says:

"Indeed a careful examination of the whole and clearly shows that its object is, as already indicated (1) to prevent deceit and false pretenses in the sale of food and drugs, and (2) to safeguard the public health."

The case further states with reference to the interpretation of the statute:

"The general language should not be so construed to [fol. 195] ruin a legitimate business and yet remedy none of the evils the statute was designed to remove."

In the language of the Supreme Court of the United States in Holy Trinity Church v. United States, 143 U.S. 457, 459, 12 Supreme Court 511, 512, 36 Law Ed. 226:

"It is a familiar rule that a thing may be within the letter of the statute and yet not within the statute because not within the spirit nor within the intention of its makers."

"This is not the substitution of the will of the Judge for that of the Legislator, for freqeuntly words of a general meaning are used in a statute, words broad enough to include an act in question, and yet a consideration of the whole legislation or the circumstances surrounding its enactment, or the absurd results which follow from giving such broad meaning to the words, makes it unreasonable to believe that the Legislator intended to include the particular Act. (Holy Trinity Church vs. United States, 145 U.S. 457, 459, 12 Supreme Court 511, 512, 36 Law Ed. 226.)

The Supreme Court of the United States in concluding the case just above recited used this language:

"It is the duty of the Courts under those circumstances, to say that however broad the language of the statute may be, the act, although within the letter, is not within the intention of the legislature, and cannot come within the sta-u-e.

[fol. 196] It follows from a consideration of the Legislative History and the evidence that the record fails to establish a lawful basis for deleting Red 32 from the list

of colors as listed in Section 136.3 of the Regulation, in that there is no evidence of record that this color, when ingested in the quantities likely to be ingested under normal conditions of use is capable of producing any harmful effects. Therefore, we say the showing is that under such uses it is "harmless". On the contrary there is affirmative evidence that it is clearly not capable of producing any harmful effects when used for the purpose of coloring oranges, the primary and virtually exclusive use of this color.

The suggestion that normal conditions of use of a color is the proper criteria on the basis of which harmlessness and suitability for use is determined for the purpose of the provisions of Section 406 (b), is also supported by the legislative history of this provision of the law.

Legislative History

In considering the legislative history of Sections 402 (c) and 406 (b) one should start with the related provisions of the Food and Drugs Act of 1906. Their practical administration prior and up to the enactment of the Federal Food, Drug and Cosmetic Act of 1938 should also be considered.

Doctor Campbell at the hearing on S. 1944, Dec. 7 and 8, 1933, used this statement:

"These regulations established the practice of examining [fol. 197] and certifying the *purity and safety* of coal-tar colors as a method for the protection of the public.

It is desirable that it be continued. In this language we are asking for legislative confirmation of a practice which has existed since 1907. (Italics ours.)

The Committee Report accompanying S. 5 (Senate Committee Report No. 361, 74th Congress, 1st Session, and set forth in full in our original brief used in these words:

"Under this procedure those colors which were *demonstrated to be without adverse physiological action*, and which from a technical standpoint were suitable for use as food colors, were admitted to certification."

"Individual batches of these particular colors were then certified by the Department after examination which

demonstrated their freedom from toxic impurities. This has resulted in an adequate supply of harmless colors for all food uses and has operated to the satisfaction of the industry.

You will note here that the Senate Committee construed as "harmless" "those which were demonstrated to be without adverse physiological action".

On the same Bill the House Committee Reported:

"Subsection (b) of this section specifically authorizes the listing of harmless coal-tar colors for use in food and the certification of batches of the listed colors which are found to be sufficiently free from impurities to be safe. *This* [fol. 198] *continues in effect a system of certification which has been followed almost from the beginning of the enforcement of the old food and drug law in order to make available to the food manufacturing industries adequate supplies of colors of established safety and purity.* (Italics ours.)

Record affirmatively establishes Red #32 "Harmless" and suitable for use in coloring Oranges.

Aside from the general considerations with respect to the use of Red #32 in foods generally, the record affirmatively establishes this color to be "harmless and suitable for use" in coloring oranges. Therefore any amendment of Section 135.3 of the regulations should be qualified so as to continue listing Red #32 for certification for this purpose, in any event.

It has been suggested that the Secretary lacks the statutory authority to establish a list of colors on the basis of specific food uses. This suggestion must be rejected as untenable for reasons, among others, that it is wholly inconsistent with prior practices of long standing and later continued in the administration of Section 406(b). The Secretary has obviously considered conditions of use as a criteria for listing coal-tar colors for certification, because that is the sole basis for the establishment of different classes of colors for certification as "harmless and suitable for use."

Intended use is the basic premise upon which classes FD&C, D&C; and Ext. D&C respectively, have been estab-

lished. Such is also the basis for the provisions of Section [fol. 199] 135.3(c) restricting the "lakes" of water-soluble straight colors of the FD&C list to the use of "external application to shell eggs." The same basic principle was obviously the basis for deleting "Violet No. 1 from the "D&C" list and including it in the FD&C list by Order dated June 1, 1950. The transfer of this color from the more restrictive list to the broader list is rested, in the pertinent findings of fact made in support of that Order, on the ground that the color listed for FD&C certification contained "less impurities" than formerly when it was restricted to the D&C list (Federal Register for May 11, 1950, Findings 7, 8, and 9, p. 2814).

The particular specifications for each color listed for certification, themselves, are determined on the basis of such consideration. Thus, colors which may not meet the desired degree of purity for food uses may, nevertheless, be used in drugs, and those which do not meet the required degree of purity for drug uses may, nevertheless, be used for drugs and cosmetics intended for external use. That same basic principle is also the basis for the separate treatment of coal-tar colors in the food law (Sec. 406(b)), the drug law (Sec. 504), and the cosmetic law (Sec. 604), respectively.

Any criteria other than specified uses would make no sense for, under any other criteria, a color would have to be rejected for all food uses just because it was found unsuitable for use in a single food. This would be clearly inconsistent with all prior administrative practice.

[fol. 200] The administrative practice of establishing classes of dyes on the basis of the intended use of the dye and of restricting it to such use has prevailed for nearly a half century and, as is clear from the legislative history outlined herein, was expressly recognized by Congress in enacting Section 406(b). Under these circumstances the doctrine of "Congressional renactment" is particularly applicable to any consideration of interpretation of Section 406(b). It is well established that reenactment of a statute is an implied legislative approval of administrative interpretations which may give the interpretations the force of law (See Davis on Administrative Law, 1951, Sec. 59, and cases cited).

It follows, therefore, that the Secretary may, and should continue to certify Red 32 for use in coloring oranges unless the record before her affirmatively establishes, by substantial evidence, that Red 32 is not "harmless and suitable for use" in coloring oranges. As stated, the record not only fails to establish any such thing, but it affirmatively establishes the contrary.

Reference is made to Appendix A and to Supplemental Sheet No. A1 attached hereto which shows clearly that it is harmless in the use for coloring oranges.

Conclusion

FD&C Red #32 is absolutely essential to the continuance of the Commercial practice and economically indispensable in the coloring of oranges. Thus far no other color has been developed.

[fol. 201] We respectfully submit as Doctor Vos said, and it appears heretofore in the brief, but we are using this in the summary.

"I think it is appropriate the method of use should be taken into consideration" (63)

"Yes, the amount of dye has to be considered when it is determined whether or not it is harmless." (62)

On Pages 44 and 45 he said he had no evidence as to the capability of producing harmful effects at the level of ordinary use, under normal conditions of use.

On the same pages he said that the tests were not at levels related to the levels at which the colors are actually used under normal conditions.

Some of the ingredients used in testing FD&C Red #32 came from a source not identified and not shown to be pure or coming from a source where it was used in the manufacture of Red #32.

Based on what has been said heretofore, we respectfully object to the entry of an Order abandoning the use of FD&C Red #32 for the use of coloring oranges, and respectfully request that the Secretary either send the matter back for further testimony as to whether FD&C Red #32 is harmless in the manner and extent to which it is used, or that the Secretary modify her Order so as to allow FD&C Red #32 to be used on the outside of oranges for coloring.

The Supreme Court of the United States has held

[fol. 202] "The settled administrative construction of a statute by those instructed with the duty of enforcing it, is entitled to great weight." (U.S.A. vs. C.N.S. & M R.R. Co. 288, US 1, (77 Law Ed 583); Brewster vs Gage, 280 US. 326, 74 Law Ed. 457.)

We respectfully submit that a department of the Government should apply the same regard for a long established construction on which formal hearings had been had before determining and had been recognized for more than a quarter of a century, and under which construction more than a quarter of a billion boxes of oranges (Over 256,000,000) (Exhibit 7) have been shipped, without a single complaint, and without any showing of any danger to any consumer.

We respectfully urge the continuation of the use of FD&C Red #32 on the outside of oranges for coloring.

Respectfully submitted, (S.) J. Hardin Peterson, Attorney at Law, Attorney for Users of FD&C Red #32 Named in detail in the original Brief filed in this matter.

Lakeland, Florida.

[fol. 203] SUPPLEMENTAL A-1 TO BRIEF

Food Machinery and Chemical Corporation
Florida Division

Lakeland, Florida

March 16, 1954.

FD&C Red No. 32 in Color Added Oranges

Two separate laboratories, Food & Drug Administration and the Florida Citrus Commission, have run independent analyses on color added oranges and have found that they contain only 4 parts per million of FD&C Red No. 32 on the basis of the total weight of the fruit. An average orange weighs 200 grams (about ½ lb) and contains therefore about 0.0008 grams (8 ten thousandths) of FD&C Red No. 32, all of which is of course on or in the outer peel.

In Dr. Vos' testimony, shown as Exhibit No. 4 in the Hearing held January 19, 1954, a series of experimental feeding tests were reported.

On page 1, results are recorded covering an experiment conducted in 1940 in which rats were fed a daily diet containing 0.10% FD&C Red No. 32 over an extended period of time beginning with rats which were only 21-22 days old.

On a comparable basis, assuming that a man eats an average of 4 pounds of food per day, 0.1% Red No. 32 would amount to 0.004 lbs of color or 1.8 grams. One pound is equivalent to 453.6 grams. In order to eat 1.8 grams of color (on the basis of 0.0008 grams of color per orange) a man would have to eat 2250 oranges—peel and all each [fol. 204] day. This is approximately 1100 pounds of oranges that would have to be eaten per day and is approximately 7 times a man's weight.

Another comparison might be made by assuming that a man ate 6 oranges, peel and all, per day. On the basis that a color added orange contains 0.0008 grams of color, this would amount to 0.0048 grams. By comparison with the rat feeding level of 0.1% in the diet, and a man eating 4 lbs of food per day he would have to eat 1.812 grams of dye. 1.812—0.0048—378. Thus the rats were fed at a level of 378 times as much color as a man would get if he ate 6 oranges, peel inclusive, per day. This would amount to 1134 times as much, on the basis that a man ate two oranges per day.

On page 4 of the Exhibit is reported an experiment in which rats were fed at 2.0; 1.0; 0.5 and 0.25% levels. Since at the 0.1% level a man would have to eat 2250 oranges, then at these levels he would have to eat 45,000; 22,500; 11,250; and 5,625 respectively.

Assuming on the other hand that a man ate 6 oranges, peel included, per day, then on the basis of 0.0008 grams of color per orange, the total would be 0.0048 grams. On the basis of a man eating 4 lbs. of food per day, the 2.0% level would require 36.24 grams of dye. This amounts to (36.24—0.0048) or 7550. Thus the rats were fed at the rate of 7550 times as much color as a man could get if he ate 6 oranges (peel inclusive) per day. At the 0.25% level this rate is 944.

[fol. 205] In the 1938-44 experiments reported on page 21, dogs were fed by means of capsules as much as 100 mgs

of color per kilogram of body weight per day. An average man weighs 70 kilograms (150 lbs) and therefore would consume 7000 mgs of color if fed at the same rate. Since a color added orange contains 0.8 mg of color it would take 8750 oranges for a man to get 7000 mgs of color per day. This is approximately 4380 pounds or about 29 times as much as the man weighs.

Again assuming that a man might eat 6 oranges (4.8 mg of color) per day then this represents that the dogs were fed at a level of 7000/4.8 or 1458 times as great. Yet in this report in spite of the high level of feeding, it was reported that the dogs showed no ill effects except for moderate weight loss.

Subsequent to this the same dogs were fed at the rate of 20 mg per kilogram per day for a period of 5 years with no ill effects. This is 1/5 the 100 mg level. On a comparable basis a man would have to eat 1750 oranges per day for the five year period. In this experiment the dogs were found to experience no ill effects.

In the 1952 experiment reported on page 29, dogs were fasted over night, then given 200 mg of color in a capsule, and then fed two hours later. It was reported that 8 of 10 dogs developed diarrhea. This, of course, is an unnatural way of feeding. Nevertheless, on this basis a man would have to eat 7 times or 1400 mg on a comparable basis and this would require 1750 oranges. This amounts to 875 pounds or more than 5 times the man's own weight. On the [fol. 206] basis of 6 oranges per day the dogs were fed at a level of 292 times as much as a man would get if he ate 6 oranges (peel inclusive) per day.

Dr. L. G. MacDowell, Director of Research for Florida Citrus Commission, testified that his laboratory's analysis of juice extracted commercially from color-added oranges showed that it contained 0.07 parts per million of Red No. 32. It should be pointed out that rarely, if ever, does a canning plant run 100% colored oranges. Generally the fruit is a mixture of grove-run and packing house elimination. It is true also that this trace of color gets into the juice in the course of the commercial extraction and is not in the juice prior to that operation.

It may be assumed that an individual might drink as much as 8 ozs (approximately 250 grams) of juice per day. This represents only 0.0175 mg or 0.0000175 grams (453.6

grams per pound) of color. Assuming that a man eats 4 lbs (1800 grams) of total food per day this amount of color is 0.000001% of the total daily diet. Compared with those experiments in which Dr. Vos employed feeding levels of 0.1%, this represents 1/100,000 of his lever or it might be said that his level was 100,000 times as much as a man might get by drinking 8 ozs of orange juice per day.

As stated earlier, Dr. Vos reported on page 21 and 22 of Exhibit #4 that in experiments conducted in 1938-1944 dogs were fed 20 mg of color per kilogram of body weight per day over a period of five years and no adverse effects were noted nor was there any accumulative effect.

[fol. 207] On a comparable basis a man weighing 70 kilograms would have to 70x20 or 1400 mg of dye per day. As shown above, 8 oz of orange juice might possibly contain as much as 0.0175 mg of dye. This then would represent (1400—0.0175) or about 80,000 such 8 oz drinks or 5000 gallons of juice per day. By analogy a person could drink a 5000 gallon tank full of orange juice every day without suffering any ill effects attributable to the presence of dyestuff.

On the basis of a man drinking 8 ozs of juice per day containing 0.0175 mg of color, this is only 1/80,000 of the intake which caused 'no effect' when the dogs were fed for five years.

In view of the foregoing considerations, it is submitted that the feeding levels of this dye employed in the experiments reported by Dr. Vos are fantastically greater than the amounts or levels that a person might get by eating oranges or by drinking the juice. It is clearly evident from the testimony presented at the Hearing that no evidence was submitted to show that consumption of the infinitesimal amounts of dye which might be consumed by eating color-added orange or juice therefrom has any harmful effects whatsoever.

R. D. Gerwe, Research Department, FM&CC.

[fol. 208] Copy

Mutual Orange Distributors, Redlands, California, U.S.A.

March 4, 1955.

Airmail

The Honorable Oveta Culp Hobby, Secretary of Department of Health, Education and Welfare, Washington, D. C.

Dear Madam Secretary:

Re: Color Certification

Speaking for the approximately three thousand grower members of this cooperative marketing association of California and Arizona citrus producers, this letter is sent you to be certain that in the consideration of this general subject, you understand that if there is an available certified color, our members are extremely interested in its use on fruit which, principally because of growth changes, does not have an appearance attractive to customers even though its interior qualities are of the highest.

Yours sincerely, (S.) Robbins Russel, General Manager.

RR:as

[fol 209] Before Department of Health, Education and Welfare.

In the Matter of: Amending Par, 135-3 and 135.11 of the Color Certification Regulations

Docket No. FDC 60

Petition

Comes now Frank R. Schell, of 1602 Richardson Place, Tampa, Florida, and respectfully petitions that the proceedings in the above cited matter be reopened, for the purpose of offering additional testimony and other available evidence which will disclose that, in fact and in law, the Food Color FD&C Red No. 32 is harmless within the lawful

meaning of Section 406 (b) of the 1938 Food, Drugs and Cosmetics Act, and in support of said petition respectfully shows:

(1) The said Frank R. Schell has a financial interest in the successful use of the said process and is a grower of citrus fruits, but, and far more important, he has a direct and heavy responsibility to the Florida and Texas citrus industries, arising out of the fact that he was the originator and inventor in fact of the Color-Added process for enhancing the varietal color of ripe oranges by the addition of a certified food color to the peel thereof, which process is the real target in these proceedings of Food and Drug Administration (hereinafter, for brevity, called F&DA).

The successful use of the Color-Added process in the States of Florida and Texas, during the years, particularly, [fol 210] of 1934 through 1945, was undoubtedly responsible, in large part, for the unprecedented growth of the citrus industries of those States, as the result of vastly increased production from trees planted during those years, so that, if those States be now deprived of the use of said Color-Added process; as a result of the present unjustified and unjustifiable attack thereon by F&DA, then the last case of the citrus industries of Florida and Texas will be far worse than it would have been had the Color-Added process never been invented, since the successful marketing of the huge volumes of oranges now produced in those States will be impossible should the use of the Color-Added process be, in effect, prohibited as the result of the efforts of F&DA to outlaw the certified food colors without which that process cannot be operated.

(2) The said Frank R. Schell is the only still living proponent of the Color-Added process who was actively engaged in all phases of previous efforts of F&DA to outlaw the Color-Added process, during the years 1933-1938, and should have been heard in this important matter.

(3) The said Frank R. Schell had no notice that any proceedings to decertify the Food Color FD&C Red No. 32 and thereby destroy the Color-Added process, were under contemplation by F&DA, until the formal notice that hearings had been set for January 19, 1954, was published in the Federal Register of December 19, 1953. Even the meager information thus had was accompanied by assurance that

these proceedings were not directed at the Color-Added process, and by the time the said Frank R. Schell received [fol. 211] other and correct information, it was far too late to find, employ and inform counsel as to the complexities of the case and for such counsel, if found, to make any proper preparation for the hearing held on January 19, 1954. Therefore, the said Frank R. Schell was unable to be represented by counsel at such hearing and, as a result thereof, the record is incomplete as to many facts of the greatest importance which should constitute a part of the record in these proceedings.

Wherefore, the said Frank R. Schell now respectfully petitions the Secretary of the Department of Health, Education and Welfare to re-open the proceedings in this said Docket No. FDC-60 and to fix a date for rehearing thereon at which time all of the facts essential to a decision therein that will accord with law and justice may be made a part of this record, in fairness to those industries whose very existence is now threatened by the unlawful attack being made thereon by F&DA.

Denied.

The said Frank R. Schell further respectfully shows that, if this petition to reopen be granted he can and will show that the coloring medium (FD&C Red No. 32) affects only the oily and waxy outer surface of the peel (a layer of only about 1/1000 inch in thickness) of oranges colored therewith; that the color does not and cannot penetrate the white cellulose of the peel, or the "rag, or the pulp, or the juice, other than the minute quanity (7/100 of 1 part per million) of color carried in the oil which escapes into the juice during extraction; that such coloring matter is not and cannot be [fol. 212] dangerous to human health, or other than harmless thereto; that personnel working with said FD&C Red No. 32, in the manufacture of Color-Added materials furnished to packinghouses, and in servicing the process in packinghouses, have had their clothing, their hands and their skin above the waist-line soaked with the color during working hours for months at a time, have inhaled the fumes therefrom and have ingested the said color, without any adverse effect on their health; that the amounts fed to test animals, in relation to any amounts that could ever be con-

sumed by any human being, through eating Color Added oranges, or drinking the juice thereof, or eating any food in which such color has been used, have been so excessive as to be fantastic; that such unrealistic tests have no relationship to the question of whether or not such color is "harmless" within the meaning of the statute, hence are wholly irrelevant and immaterial to the issues in this cause and should be stricken from the record; and other pertinent matters which could, and would have been shown at the hearing had on January 19, 1954, save for the fact that proponents of the Color Added process had been induced to inaction by assurances had that these proceedings were not directed at that process, receiving no information, until January 1, 1954 (far too late to make any proper preparation for such hearings), that the complete destruction of the Color Added process constituted the real objective of Food and Drugs Administration in the institution of these proceedings.

Further reasons why this petition should be granted are contained in this petitioner's Exceptions to Order promulgated on December 29, 1954, and in petitioners Brief on [fol. 213] said Exceptions, the said Exceptions and Brief being hereto attached and by this reference made a part of this Petition as fully and completely as if herein set forth verbatim.

Your petitioner further respectfully prays, should this petition be denied by the Secretary of Health, Education and Welfare, that, as alternative relief, he be admitted as a party to these proceedings and that his Exceptions to the proposed order and to the Findings of Fact filed by F&DA in support of the effort to secure promulgation of such order, and the brief by Frank R. Schell in support of his said Exceptions, all hereto annexed, be now admitted to the record in these proceedings and given the same fair and conscientious consideration as is due them and the other briefs filed in connection with said subject matter.

Allowed.

(S.) Frank R. Schell.

Tampa, Florida, 1602 Richardson Place.

March 5, 1955.

[fol. 214] In the Matter of: Amending Par. 135.3 and 135.11 of the Color Certification Regulations

Docket No. FDC-60.

Exceptions to Order and Brief on Exceptions

Foreword

In explanation of what might otherwise be considered an unnecessary digression, we respectfully submit our conviction that an impartial appraisal of the issues involved in these proceedings connot be properly approached without an appreciation and consideration of the history of prior efforts by Food and Drug Administration (hereinafter, for brevity, called F&DA) to outlaw and destroy the Color Added process, being a process for enhancing the varietal color of mature citrus fruits, particularly oranges, by the addition of an infinitesimal amount of a certified food color to the peel thereof.

We further respectfully submit our profound conviction that a careful evaluation of that prior history, together with a review of the record in the instant proceedings, will disclose that, beyond any reasonable doubt, these present proceedings constitute a renewal of similar efforts made by F&DA during the years 1933 to 1938, when, as now, the sole purpose thereof was to outlaw and destroy that process, the prior and present protestations of F&DA to the contrary notwithstanding.

[fol. 215] It is further respectfully submitted that consideration by the Honorable Secretary of the Department of Health, Education and Welfare, of the matters and things hereinafter recited, is not only right and proper, being a record of acts and things done by a subordinate Bureau of her Department, which can be verified by a careful inspection of the files of F&DA, but such consideration is required in the interest of truth and justice and of morality in Government.

It is further respectfully suggested that a review of those files may, perhaps, disclose the presently unknown and incomprehensible motive prompting this renewed attack upon the Color Added process, after more than 53 billions of oranges had been colored by the certified

food colors employed in that process, over a period of more than 14 years, without developing any slightest evidence, even yet, or eliciting the slightest complaint, that any person has ever suffered even a minor inconvenience, much less any injury or danger to their health, from eating Color Added oranges, or drinking juice from oranges colored thereby, although such juice has been a major item in the diet of, literally and actually, millions of babies.

It is further respectfully submitted that, very obviously, in these circumstances, the institution and prosecution of these proceedings by F&DA have not been grounded upon any possibility of injury to the public health, nor upon any necessity of protecting the public against fraud. Since the powers delegated to F&DA by the Congress are restricted to authority to prevent dangers to the public health and prevention of fraud, F&DA are, in this matter, acting without authority in law, and should be brought [fol. 216] back to a realization that F&DA, like all other agencies of Government, and all individuals, are bound by the law—not by their prejudiced conception of how the law should read—a fact which F&DA have ignored and flouted in these proceedings.

Nature and Early History of the Color Added Process

The Color Added process, in its simplest embodiment, comprehends a colloidal dispersion of a small amount of an appropriate oil-soluble, water-insoluble, certified food color, in on aqueous solution of soap and water, plus, in some instances, a small amount of solvent for the dye. The fruit is submerged in the coloring medium, or the coloring medium is sprayed on or poured over the fruit, for a period of several minutes, the coloring medium being maintained at a constant temperature of not to exceed 123°F.

The oil-soluble food color is absorbed by, or penetrates, *only* the very thin (about 1/1000 of an inch) layer of oily and waxy materials in the extreme outer covering of the peel. The oil-soluble color is chemically and physically incapable of coloring the white cellulosic material of the peel, or the white "rag" (membranes) of the interior, or the pulp, or the juice, being insoluble therein. An

infinitesimal amount of the oil-soluble color (about 7/100 of 1 part of color per million parts of juice, by weight) is sometimes carried into the juice in peel oil that escapes into the juice during extraction.

Conversely, the water-soluble, oil-insoluble colors are chemically and physically incapable of impregnating these [fol. 217] oily and waxy constituents of the peel with an added color, these waxy and oily materials being Nature's water-repellent safeguard against the fruit becoming water-soaked by rains, etc. But the water-soluble colors will color the white cellulosic constituents of the peel and, for that reason, a contrasting water-soluble color, usually green, is sometimes used in the Color Added process to mark breaks in the peel from clipper cuts, scratches, etc. enabling easy detection and elimination of such damaged fruits.

In the early months of 1933, the Color Added process was being redied for commercial use. Full information was given to Mr. Walter G. Campbell, then Chief of the Food and Drug Administration, a part of the Department of Agriculture, as to the materials in and use of the process, as above outlined. No objection by that Bureau had been anticipated, because the artificial coloration of mature citrus fruit had long been approved and promoted by the Department of Agriculture, which had determined and publicized the necessity for such artificial coloring practices, as witness the following excerpts from the official publications of that Department:

"Some of the early fall varieties of oranges and grapefruit ripen while the fruit is still green in color. Later varieties that mature in the spring or summer assume the color of full maturity during the winter while the fruit is still immature, but when warm spring weather occurs the rind may turn green again. Thus while the edible part of the fruit ripens, there is a 'regreening' of the rind. Grapefruit growing inside of densely foliated trees never develop full color, although some of the best-flavored fruit [fol. 218] is produced there. *There is, therefore, no definite relation between flavor or maturity and the color of the fruit while on the tree. However, there is a very significant relation between the color of the fruit offered for sale and the price that it will bring, and citrus fruit producers have*

always faced the problem of making the color of ripe fruit match its flavor." (Yearbook, U. S. D. A., 1932, pp. 134-137; emphasis ours.)

"It is well known that citrus fruits grown under certain climatic and cultural conditions may be mature and highly desirable for food while the skin of the fruit is still green in color. This is especially true of the Satsuma orange as grown in Alabama, where the fruit frequently reaches a state of physiological maturity at which it is palatable and attractive as an article of die some weeks before it attains the characteristic golden yellow color. In general, when it reaches full color on the trees the fruit in this region is characterized by a low acidity, with a comparatively high sugar content, and the overripe fruit is inclined to be insipid in flavor. It is important then, if this fruit is to be furnished to the consuming public in its most desirable condition for food, that it be harvested before it becomes yellow on the trees.

"* * * *On the other hand, green colored fruit, no matter what the quality, is difficult to merchandise. In the mind of the consuming public a green colored orange is immature and unfit for food.* * * * The green colored fruit is therefore at a decided disadvantage in competitive selling. *It is evident, then, that some method of treating this fruit so that it would assume a rich orange-yellow color early in the season, when it is most desirable for food, would be of* [fol. 219] *benefit to the industry and to the consuming public alike.*" (U. S. D. A. Bulletin 1159, August, 1923; emphasis ours.)

"The practice (artificial coloring of citrus) originated in California. It was first applied to the coloring of lemons and later adapted to oranges, particularly to Valencias, which have a tendency to become green late in the season, even though they have once assumed the golden-yellow color. Nearly all packing-houses are equipped with some facilities for coloring. At some seasons with certain kinds of fruit, it is a very common practice and considered one of the essential operations in preparing it for market. * * * (Parenthesis ours.)

"From a careful survey of the field, apparently *there was no basis for the conclusion that the color of citrus fruit is an indication of its dessert quality* or attractiveness as

an article of diet. * * * The color of the skin of the fruit when it has reached this stage in its development is partly a varietal characteristic and partly dependent upon the climatic and cultural conditions under which the fruit is grown. *It is obvious, then, that treating fruit which is physiologically mature* or has reached a state in its development at which it has high dessert quality, *so that it assumes a color or appearance pleasing to the eye* and has a higher decorative value, *is a legitimate practice in marketing and one which should be encouraged.*" (U. S. D. A. Bulletin 1367, May, 1926; emphasis ours.)

The ethylene gas process for "degreening" citrus fruit, then in universal use, had been invented and dedicated to the public by Dr. Frank E. Denny, of the Department of Agriculture, in 1923.

[fol. 220] The Color Added process had been necessitated by the fact that there is one variety of orange, produced in one competitive citrus growing area, which will attain an excellent but completely artificial color from the use of ethylene gas alone. While one of the orders of the Secretary of Agriculture, in the proceedings hereinafter recited, stated that the only effect of the ethylene gas process was to "unmask" the natural varietal color of the fruit, already present underneath the green, this statement was wholly incorrect. The color of that particular orange (produced in that one area) as disclosed when the green color first disappears, is the same pale, sickly-yellow found at that stage of processing on all other oranges produced in that area, and on all oranges produced in all other citrus producing areas. However, further exposure to ethylene gas, after all of the green coloration has disappeared, results in that particular orange attaining the rich orange-red color before mentioned, while additional exposure to the gas of all other varieties produced in that area, and of all oranges produced in other areas, results in no appreciable improvement in color.

As above stated, it was not anticipated that F&DA would or could have any possible objection to the use of the Color Added process, since it merely met the compelling necessity of citrus producers in all other areas to equalize the competitive advantage enjoyed by the producers and shippers of the orange which attained that most desirable

artificial color from ethylene gas alone. The Supreme Court of the United States had long before laid down the principle that it is the change in color, not the means employer, which is pertinent, even when that change constitutes but a removal of color.

[fol. 221] To our amazement, and consternation, Mr. Campbell promptly ruled that, if our process were permitted to be used at all, the oranges so colored, would have to bear a label, not on the wrappers and boxes alone, but on the peel of the orange itself, indicating the presence of the food colors used. That was bad enough, but, soon thereafter, Mr. Campbell advised us that any use of our process would be prohibited, whether or not the fruit was so labeled.

In May of 1933, this writer went to Washington and employed the firm of Palmer, Stellwagen and Scott to represent us in these proceedings before the Department of Agriculture, and to defeat the stated purpose and intent of Mr. Campbell to outlaw the Color Added process.

While, as above stated, it had never occurred to us that F&DA would show a preference for one method of ar-ific-ally coloring citrus fruits over another process for accomplishing the same result, we soon discovered that F&DA and the producers of that one orange which attains an excellent artificial color from ethylene gas alone, were working closely together, as allies, to outlaw our process, which result would, of course, retain for those producers their prior monopoly of a satisfactory artificial color, with its almost unbeatable sales advantage. We did not blame those producers for trying to retain that advantage, any more than we would blame them if it develops that they are involved in this present attempt to destroy Color Added, which is quite possible. But we did censure F&DA then, as we would censure F&DA today, for improperly and secretly aiding either side in a competitive struggle wherewi-h no one in Government should be concerned.

[fol. 222] On October 31, 1933, our brief was filed. It was never answered, being unanswerable. On February 28, 1934, the Solicitor of the Department of Agriculture addressed to Secretary Wallace his opinion that -he coloring of oranges by either the ethylene gas process or the Color Added process constituted adulteration, but further finding that, as to both processes, such adulteration could be cured

by appropriate labeling. In our case that meant stamping the words "Color Added" on the peel of the orange (that wording being used because it was not possible to make a die for use on small sizes which could carry the words "Artificially Colored" in the required type size) while fruit colored by ethylene gas alone would carry "Colored by Gas" or similar wording.

On March 9, 1934, in a letter to Mr. A. Mitchell Palmer, Secretary Wallace approvingly quoted this opinion of his Solicitor.

On July 16, 1934, after further argument and discussion, Mr. Wallace handed down his decision to the effect that oranges colored by the Color Added process must bear that labeling, but that oranges colored by the ethylene gas process would not have to be thus labeled, for the incorrect reason above recited.

It would seem that this should have put an end to the controversy, since this writer declined to institute Court proceedings challenging that order, the reason for so declining being that all early and late species of citrus fruit (not just oranges) in all citrus-producing areas are necessarily harvested with a green peel. It was realized that if we forced the issue in Court the result would, in all [fol. 223] probability, be the imposition of a label reading "Colored by Gas," or "Gas Treated," on all citrus fruits and, perhaps, other fruits such as bananas, apples, pears, etc., all of which are ethylene treated, since, under the law as above mentioned, it is the fact of a change in color, and not the means whereby that change is accomplished, which is pertinent and controlling.

We could not be sure that it would be at all possible to successfully market the large and increasing volume of citrus and other fruits with such labeling, and this writer would not risk injury to and, perhaps, the destruction of, the entire citrus industry and other fruit industries of the United States. Accordingly, from the first commercial use of our process, oranges so colored have borne the label "Color Added," while that particular orange, above mentioned, produced in that particular area, beautifully but artificially colored with ethylene gas alone, has gone unlabeled.

Mr. Cambell, however, did not abide by that order of Secretary Wallace, but continued his efforts to destroy the

Color Added process. There were further and continuing hearings before the Department of Agriculture in the fall of 1934, again in 1935, in 1936 and, finally, in 1937. Following this last hearing, Mr. Wallace, in about August of 1937, issued his final order, indefinitely postponing the effective date of an order outlawing the Color Added process, which order had issued on November 25, 1935, effective September 1, 1936, but had thereafter been postponed to become effective on September 1, 1937. With the issuance of that last order, Mr. Campbell ceased his attempts to persuade Mr. Wallace to go along with his fanatical prejudice against the use of any artificial color in or on any food.

[fol. 224] However, Mr. Campbell had not been relying upon only one string to his bow. While vigorously fighting the Color Added process, from early 1933 until August of 1937, in the Department of Agriculture, Mr. Campbell, ably and diligently assisted by Dr. Paul B. Dunbar, his principal assistant and successor in office, was fighting the Color Added process with every other weapon at his command. In 1935, he instigated the imposition of State embargoes against Color Added oranges by two States, and we barely escaped imposition of embargoes in a number of other States. We were able to fight off all of those embargoes because the State of Florida, at the first session of its Legislature after Color Added had gone into commercial use, had, at the instance of the Florida citrus industry and this writer, enacted its "Color Added Act," which imposed materially higher standards of maturity and quality for Color Added oranges than were required for oranges not so colored and very rigid State inspection to enforce these standards. (Those standards have been further raised, by later enactments, always at the instance of the Florida citrus industry, until, today, they constitute the highest standards of equality, not mere maturity, which any industry, producing any item of perishable fruits or vegetables, has ever imposed upon itself as to any such product, at any time, in any State.)

Again, there had been introduced in the Congress, in 1933, a proposed new Food, Drug and Cosmetics Act, which had powerful New Deal support. That 1933 bill carried language which would have empowered F&DA to outlaw

the Color Added process. Fortunately, however, it also carried other provisions which were so obnoxious as to [fol. 225] cause the proposed bill to be denounced by a number of Members of the Congress on the grounds that it would make F&DA the absolute dictator of the food, drug and cosmetic industries of the United States.

It must be recalled that there were not, in that Congress, very many Senators or Representatives who had not had forcefully called to their attention, by their constituents, cases in which legitimate business had been harassed by arbitrary and capricious acts of F&DA. Again, it should be further borne in mind that the Federal Courts had, on a number of occasions, rebuked F&DA for arbitrary and capricious actions and for attempts to expand its powers beyond those granted by the Congress.

In consequence of all of these things, that 1933 bill very fortunately failed of enactment.

Successive proposed Food, Drug and Cosmetics Acts were introduced in each session of the Congress, to and including the year 1937. While each succeeding proposed bill was a bit milder than the preceding bill, as to broader powers sought, each still contained provisions which could have been used by Mr. Campbell to destroy the Color Added process, and he and Dr. Dunbar contended mightily therefor.

That they were unsuccessful was largely due to the fact that, by such times, Mr. Campbell was well known to be an absolute fanatic on the subject of added artificial color in or on any food product—a fanaticism which has quite evidently persisted in F&DA to this day. For example, Mr. Campbell had attempted to procure the enactment, in the first of his proposed FD&C bills, of a repealer [fol. 226] of the Act of Congress of 1886 whereunder added artificial color is defined as a legal component of butter, which definition had been extended, by analogy, to cheese, no label declaration of the presence of such added color being required. This attempted repealer brought the dairy industry of the United States into opposition to Mr. Campbell's attempts to create for F&DA a dictatorship over the food, drug and cosmetics industries of the United States. In consequence, aroused representatives of affected industries were able to block enactment of all of these several proposed new bills.

The fanaticism of Mr. Campbell on this subject of artificial color in or on foods was well illustrated at a conference between that gentleman and our counsel, Messrs. A. Mitchell Palmer and Seiforde M. Stellwagen, at which conference this writer was present, which conference was held in about June of 1933. Mr. Campbell stated, very frankly, at the opening of the conference, that he was unalterably opposed to the use of any artificial color of any kind or character in or on any food product whatsoever, and, accordingly, was unalterably opposed to permitting the use of our Color Added process.

Mr. Palmer thereupon inquired whether that opposition would extend to the little vials of food colors which mothers buy to tint the icing on birthday cakes for their children. Mr. Campbell replied that the cake would taste just as good without any artificial color—a statement of doubtful authenticity, since it is well known that an article of food bearing an appealing color will be more appetizing than one without eye-appeal.

[fol. 227] Mr. Palmer then reminded Mr. Campbell that all of these colors were manufactured from base colors which Mr. Campbell's Bureau had certified as harmless and suitable for use in foods and that the use thereof had been recognized and approved for years. To this Mr. Campbell replied that whether or not the food colors were lawfully manufactured and sold was not the pertinent point; that the use of any food color in or on any food product was morally wrong and should be prohibited by law and that, if Mr. Campbell was successful in the efforts he then had under way, that result would ensue; that, for that reason, he was unalterably opposed to the Color Added process and did not intend to permit its use if at all possible to prevent the same.

The battle over the proposed new Food and Drug bills persisted until, in 1937, the bill known as S-5 (being the same number carried by the 1938 bill) was passed by both Houses of the Congress but, although the differences between the House and Senate bills were insignificant, still failed of final passage.

Thereafter, Mr. Campbell called on the Hon. J. Hardin Peterson, Representative from the First Florida Congressional District. He came, to use his own words, "with his

hat in his hand," stating that he knew when he was licked and had as well take his medicine gracefully; that if the Florida and Texas citrus people would cease their opposition to the passing of a new Food, Drug and Cosmetics Act, then, so far as he was concerned, those people could rewrite, to suit themselves, those parts of the proposed bill which they deemed inimical to the welfare of the citrus industry.

[fol. 228] Mr. Peterson telephoned that information to this writer on that same evening, and a delegation from the Florida citrus industry, including the writer, promptly went to Washington, there participating in conferences held by our attorney, Mr. Stellwagen (Mr. Palmer had died in 1936) with Mr. Campbell. Agreement having been had on necessary changes in language—and such agreement was readily reached—the others of the Florida delegation returned home, the writer remaining in Washington until the bill had been rewritten in final form.

There was a final (termed "buttoning-up") hearing by a Committee of either the House or the Senate, which was attended by Mr. Campbell, representatives of the dairy people, the drug industry, Mr. Stellwagen, this writer, and, as we recall it, some representatives of the cosmetics industry.

Because it was, as someone present termed it, "our last shot at the bear," the new bill was read and discussed almost paragraph by paragraph, requiring considerable time. Mr. Stellwagen, having a previous appointment, was forced to leave before the hearing was over, and asked this writer to remain and report to him on anything of importance thereafter transpiring.

We reached, finally, what is now Paragraph (b) of Section 406, regarding the certification of coal-tar food colors. Someone present—my recollection is that it was one of the drug people—inquired as to whether or not it would be advisable to define the word "harmless" as used in that sub-section. This writer immediately asked to be heard and stated that it was his understanding that all of [fol. 229] the prior decisions of the Courts interpreting, construing and applying the provisions of the 1906 Act, as amended, would be continued in full force and effect and be fully applicable in all future litigation under like pro-

visions of the new law; that the word "harmless" had been construed, over and over again, by those Courts hence, if these decisions were to continue in effect, there was no occasion for defining the word "harmless" in the new Act, but, if the new bill would have the effect of revoking those prior decisions, then that language should be enlarged to include that definition laid down by the Courts.

Mr. Campbell then took the floor, agreeing with the statement just made by this writer and stating that he was agreeable to such definition of the word "harmless" being inserted if desired, but that he, too, was under the distinct impression that the prior decisions of the Courts were to be preserved in full force and effect and would not be in any wise affected by the new law except where there was a specific repealer or other specific change that clearly voided a prior decision by the Courts on that particular point. Mr. Campbell went on to say, with considerable force and emphasis, that it was vitally important that the new bill should not affect that great mass of the law already embodied in prior decisions of the Courts; that, if those prior decisions were abrogated by the new act, it would then be necessary for his Department to re-establish, as precedents, each of the principles theretofore laid down by the Courts and that such an undertaking would require years of work and millions of dollars of unnecessary expense; that [fol. 230] he would have to request that his budget for F&DA enforcement services be at least tripled if F&DA was to be compelled to re-establish those old and controlling principles in every case that came up under the new law.

There was entire agreement among all present that those prior decisions of the Courts should not be disturbed by the new bill. The presiding officer then stated that he thought that it was clearly understood, and that it was certainly the understanding and intent of that Committee, as it would be the clear intent of the Congress, in enacting the new law, to retain and preserve in full force and effect the pertinent prior decisions of the Courts, making them fully applicable in future cases arising under like provisions of the new act. Accordingly, no definition of the word "harmless" was written into paragraph (b) of Section 406.

It is not the intent of this writer to say or imply that he has quoted the exact language used, but he does assert,

and would be only too happy to be sworn and to testify, that the foregoing is a fair and correct statement of what transpired in connection with that particular paragraph of the new law on that occasion.

It is Mr. Peterson's recollection that the minutes of the 1938 hearings were not printed, because prior hearings on the old bill S-5, which had failed of passage in the fall of 1937, had been voluminous, and it had been agreed that the record of hearings held on the old bill would be adopted as the record for the new bill. Most unfortunately, Mr. Peterson has been unable to locate the typewritten minutes [fol. 231] of any of the hearings on the new bill (some of which were more of the nature of informal conferences than formal hearings), including the minutes of this last "buttoning-up" hearing. However, should the Department of Health, Education and Welfare so desire, that record can be supplemented by sworn testimony, which is another reason why this writer's petition for re-opening this case, taking additional testimony and introducing additional evidence, should be granted. However, it is very likely that the foregoing statements will be completely substantiated by the records kept in Mr. Campbell's office at that time, F&DA having since cited and relied on those prior decisions.

Despite the fact that Mr. Campbell and Dr. Dunbar had fought the Color Added proces vigorously, with every weapon they could lay hands on, from the early months of 1933 until agreement was had with the Florida and Texas citrus people on the provisions of the 1938 Act, it is to be noted that, once made, both Mr. Campbell and Dr. Dunbar kept their agreements religiously. There will be found in the files of F&DA a letter written by Mr. Campbell to one of the State enforcement officers, stating, in effect, that the matter of legitimacy of the Color Added process had been settled by Congressional action when the Congress enacted the 1938 Food, Drug and Cosmetics Act, in which it recognized the propriety of the Color Added process, and that, so long as the States of Florida and Texas policed their own industries and enforced the standards contained in State laws and the oranges carried the "Color Added" label, Mr. Campbell had no further interest in the Color Added process.

[fol. 232] Mr. Campbell gave similar assurance to a Florida citrus shipper at about that same time, but it is my recol-

lection that this last statement was made verbally, rather than in writing.

From that day in 1938—until sometime in the fall of 1952—something over fourteen years—by neither word or deed did F&DA ever indicate any opposition or enmity toward the Color Added process.

It is greatly to be regretted that the present officers of F&DA have seen fit to repudiate solemn agreements entered into by their predecessors in office and are now attempting, without rhyme or reason, much less authority in fact or in law, to bring about the abolition of that process, notwithstanding their admitted knowledge that the process cannot be dangerous to human health and that the continuing use of that process is imperatively required if the citrus industries of Florida and Texas are not to be destroyed.

That the present officials of F&DA have made this attempt gives rise to a question as to the real motive prompting their action.

We respectfully suggest and urge that the Department of Health, Education and Welfare institute a strict examination to determine that motive—that is, whether this attempt has been motivated by a flare-up of the old fanaticism against the use of artificial color in or on any food, or whether this is another attempt to increase the powers of F&DA to the point where it will have attained that dictatorship over the food, drug and cosmetics industry for which it contended so vigorously from 1933 into 1938.

[fol. 233] It hardly needs mentioning that, if F&DA can establish their interpretation of the word "harmless," as contended for in these proceedings—i. e., that no food color is harmless within the meaning of the law if F&DA pharmacologists can make any living creature ill by overfeeding and force feeding that animal with massive and fantastic amounts of the color, administered under unnatural conditions—then it is but one short step to applying that precedent and that interpretation to every other substance coming within the purview of the 1938 Food, Drug and Cosmetics Act, when that absolute dictatorship will have been attained.

The Secretary may find, of course, that these proceedings stem from a revival of the old alliance between F&DA and

other citrus interests, and that a corollary purpose of these proceedings may be to re-establish, for that old ally, its prior monopoly of a satisfactory artificial color for oranges, along with the above mentioned accruals to F&DA.

All of which, together with our Exceptions and Brief on Exceptions, which follow this Foreword, are

Respectfully submitted, Frank R. Schnell.

EXCEPTIONS TO PROPOSED ORDER AND TO FINDINGS OF FACT FILED BY FOOD AND DRUG ADMINISTRATION IN SUPPORT OF SAID PROPOSAL.

Exception No. 1: The Proposed Order is without authority in law.

Denied.

[fol. 234] Exception No. 2: The Proposed Order and the Findings of Fact filed in support thereof, are without foundation in fact.

Denied.

Exception No. 3: These proceedings were not initiated in good faith, nor have they been so conducted, by Food and Drug Administration.

Denied.

BRIEF

Exception No. 1: The Proposed Order is without authority in law.

Denied. See Conclusions 1-4.

This writer is no lawyer, hence is leaving the citation of cases and the like to the lawyers. However, having lived through twenty years of experience with Food and Drugs Administration, he is not uninformed as to the pertinent principles of law with which we are here concerned.

(a) The Proposed Order is not necessary for the protection of public health, hence the attempt to promulgate the same constitutes an attempt at usurpation of power by F&DA.

The Constitution of the United States reserves the general police powers over our people to the several States and, save for that reservation of powers in the several States, the Constitution, as written in 1787, would not have been adopted by the delegates to the Constitutional Con-
[fol. 235] vention, as is clear from the proceedings of the said Constitutional Convention, nor would it ever have been ratified by the original thirteen States. That reservation of powers has never been altered or repealed.

Therefore, the usages of such police powers as are enjoyed by the Federal Government, insofar as we are here concerned therewith, are strictly limited to such procedures and actions as may be required for protection against dangers to the public health (or against fraud upon consumers, with which latter clause we are not here concerned) arising out of the interstate transportation of articles of food, drugs and cosmetics, and such danger must be real and apparent, not wholly fanciful and imaginary, as is the nature of the alleged dangers inveighed against by F&DA in the instant case.

Whenever F&DA thus departs from that rule, it is the duty of the Department having supervisory powers thereover to bring its subordinate bureau back into line, with an appropriate reminder that we are living under a government of laws nd not of men, from which laws F&DA are in no wise exempt.

As will hereinafter be shown, the real purpose and intent of F&DA, in these proceedings, is to outlaw the aforesaid Color-Added process. F&DA are, or should be, estopped from prosecuting such purposes and intent for the reason that in a letter to Hon. George A. Smathers, U. S. Senate, dated February 7, 1955, and signed by George P. Larrick, Commissioner of Food and Drugs, the following statement is made in the last paragraph of that letter:

[fol. 236] "The proposal to remove these coal-tar colors, including FD&C Red No. 32, from the list of colors eligible for certification for use in food results from the requirement of the Pure Food Law that only colors that are harmless are eligible for certification. Recently investigations show that these colors, when fed in *substantial* amounts, show evidences of toxicity. *There is, however, no evidence that, in the amounts used, and in the manner of use, in the*

coloring of citrus fruit, the product so colored is not safe for human consumption." (Emphasis ours. "Substantial" might well read "fantastic".)

(b) The Proposed Order is premised upon an attempted unconscionable interpretation by F&DA of the word "harmless" as used in Section 406 (b) of the 1938 Food, Drug and Cosmetic Act. As is clearly disclosed by the record of the hearing of January 19, 1954, it is the contention of F&DA that no color is "harmless," within the meaning of that Section of the Act, if F&DA pharmacologists can make any living creature ill by force-feeding massive and wholly fantastic doses of said color to such creature, under wholly unnatural conditions prescribed by F&DA's pharmacologists.

It is respectfully submitted that even pure water could not qualify for certification as "harmless" if such a weird construction of that word were permissible. It is a well settled fact of medical science that every living creature has a limit of tolerance for any and every substance that may be ingested by such creature and that if any substance be fed to any creature in excess amounts, then that creature will be made ill thereby, even though that substance be [fol. 237] pure water or pure proteins, which, taken in proper proportions, are the substances of like itself.

The contentions of F&DA in these records are contrary to all of the provisions of law governing the construction of language used in statutes since, without exception, it is required that the construction applied to a particular word in a particular statute must be a "reasonable construction" and in consonance with the purpose of the statute, which, in this case, is the protection of the public health, which F&DA, as above shown, have admitted is not and cannot be endangered by the consumption of the food color concerned through eating oranges colored therewith or drinking the juice from oranges so colored.

It is to be noted that a principal and most important use of F&DC Red No. 32 is its use for coloring oranges and that F&DA were formally advised, by representatives of the manufacturers, that they stand ready to restrict the use of that color to that purpose exclusively. F&DA has the power to so restrict its use and no objection would be entered to such restriction by proponents of the Color Added

process, although the record clearly discloses that consumption of the color, for any purpose, in any usual or customary amounts, could never be injurious to human health.

(c) The Courts have held, in many cases, that the "practical interpretation" or construction of doubtful or ambiguous language in a statute, which has been acted upon by the Department charged with its enforcement, will not be disturbed save for weighty reasons (See 280 U.S. 327).

[fol. 238] From 1938 until 1952—14 years—the interpretation placed upon the word "harmless" by F&DA was that the substance concerned must be "harmless when consumed in the amounts and under the conditions of normal usage thereof" and F&DA have admitted that under that construction of the word "harmless", which F&DA gave thereto and consistently followed for all of those 14 years, the colors used in the Color Added process are completely harmless to human health. No weighty reasons—not even possible reasons—for upsetting that interpretation, at this late date, have been even suggested by F&DA, in these proceedings or elsewhere.

On the contrary, the complete absurdity of F&DA's contentions herein is illustrated and emphasized by the recent promulgation, by F&DA, of tables of tolerances for poisonous spray residues permitted to remain on fresh citrus fruit as sold to consumers. By those tolerance tables, F&DA permits such citrus fruits to bear 7 parts per million of arsenate of lead, a known deadly poison of known cumulative properties.

Thus F&DA is saying that the public health will not be endangered by eating oranges that carry, on the peel, seven parts per million of that known deadly poison, of known cumulative properties, but will be endangered by consuming oranges that carry, on the peel, four parts per million of a food color which it has certified, and for fourteen years permitted to remain certified, as being harmless and which the tests run from 1938 through into 1944, put in evidence by F&DA (and F&DA is bound thereby) conclusively demonstrate to be without either immediate or cumulative toxic properties.

[fol. 239] Where, then, are the "weighty reasons" required to support F&DA's fanciful theory, conceived just

14 years too late, that the Congress of the United States, by solemn enactment, authorized, and instructed, in Par. 406 (a) the fixing of tolerances for deadly poisons, then, in the very next paragraph of the same Section, forbade the use of any food color, however harmless under usual conditions of usage, if F&DA pharmacologists can make some living creature ill by force feeding that creature with huge and fantastic amounts of that color, ingested under unnatural conditions.

Those tolerances for poisons and the requirement for certification of food colors are contained in the same Section of the 1938 Act (406 (a) and 406 (b)). Certainly a strong argument can be made for (stronger than can be made against) the proposition that the provisions of Par. 406 (a) are applicable to the second paragraph of the same Section.

(d) Again, it is well known (being a fact whereof the Department of Health, Education and Welfare is charged with knowledge, since it is undoubtedly reflected by the files of F&DA for the year 1938) that the chief of F&DA, in Congressional Committee hearings on the 1938 Food, Drugs and Cosmetics Act, vehemently insisted that the great body of law contained in prior decisions of Courts of Competent jurisdiction, when interpreting the 1906 Act, as amended, must not be revoked or in anywise disturbed by the enactment of the 1938 Act, since, were those prior decisions negatived by the new Act, years of time and heavy and unnecessary expense would be required to re-establish, as precedents, the principles laid down by those earlier [fol. 240] decisions of the Court. There being no dissent from any other person present at those hearings, the Chairman announced that everyone, including members of the Committee, were in entire accord on the point that it would be the intent of the Congress to preserve, in full force and effect, the prior decisions of the Courts, when interpreting the 1906 Act, as amended, making the same fully applicable when construing like provisions of the new Act.

It is unfortunate that the minutes of those hearings have apparently been lost, but this writer was present and heard Mr. Campbell's argument to that effect and the files of F&DA for 1938 will undoubtedly support these statements.

as will the records of subsequent cases prosecuted by F&DA, in which such prior decisions have been cited and relied upon by F&DA.

In numerous decisions, the Courts, interpreting the 1906 Act, held that before F&DA might interfere with the manufacture, transportation or sale of any properly labeled article of food or drugs transported, or offered for transportation, in interstate commerce, it must be shown that such article of food, or drugs, was injurious to human health when used or consumed in the amounts and under the conditions of normal and ordinary usage thereof.

F&DA are, therefore, in these procedings, attempting to repudiate, not only their own construction of the word "harmless" which they had applied to that word for fourteen years, but are also attempting to repudiate their own insistence that the prior decisions of the Courts in interpreting the 1906 Act, as amended, should apply with like [fol. 241] force and effect to similar provisions of the 1938 Act, both of such attempts being contrary to law.

To Summarize: The Courts have said, plainly, on many occasions:

(1) That Constitutional limitations restrict the activities of F&DA to those necessary to protect against dangers to the public health and danger of fraud on the public, with neither of which dangers we are here concerned.

(2) That the language of a statute must be given a reasonable construction;

(3) That F&DA may not lawfully interfere with the manufacture, transportation or sale of any properly labeled substance contained in or on foods or drugs, absent a showing that the same is or could be injurious to human health when consumed in the amounts and under the conditions of ordinary and normal usage. Mr. Walter G. Campbell, Chief of F&DA, vehemently contended, in 1938, that the prior decisions of those Courts, construing the 1906 Act, must be preserved and made applicable in cases arising under like provisions of the 1938 Act;

(4) That the long continued interpretation or construction of doubtful or ambiguous language in a Statute, which construction has been acted upon by the Department charged with its enforcement, will not be disturbed save for weighty reasons. That construction for which this writer contends,

i.e., that the word "harmless" as used in the 1938 Act means [fol. 242] "harmless when consumed in the amounts and under the conditions of ordinary and normal usage", was first applied to that word by Mr. W. G. Campbell, Chief of F&DA, principal author and proponent of the 1938 Act, and by Dr. Dunbar, who was Mr. Campbell's principal assistant and successor in office. Certainly, Mr. Campbell and Dr. Dunbar were fully and completely informed and advised as to the intent of the Congress in its use of language, and, accordingly, of the proper interpretation and construction to be given this word "harmless" when used in connection with the certification of needed food colors. Yet, after fifteen years (1938-1953) of following such construction, without question, their successors now, without the required weighty reasons, or other excuse therefor, would reverse that construction, contrary to law.

Clearly, no justification can be found in law for the nonsensical statements of F&DA that they are compelled, by law, to contend that no food color is "harmless" within the meaning of the Statute if F&DA can make some living creature ill by force feeding that creature with fantastic dosages thereof, by means which constitute cruelty to animals.

Denied. See Findings 2-10.

Exception No. 2: The Proposed Order and the Findings of Fact filed in support thereof, are without foundation in fact.

We believe that, in view of the foregoing, it must be conceded that, for this propsed order to stand, it must be shown that the colors concerned are harmful to human [fol. 243] health, or offer a danger to human health, when consumed in the amounts and under the conditions of ordinary and normal usage, and that such danger must be present and real, and not some visionary or fanciful possibility, based on empirical experiments which bear no relation to reason.

It should be sufficient to invalidate the proposed order to cite the admission by Dr. Voss that no attempts have been made to relate the results of the experiments conducted on various animals to some showing of danger to human health and that F&DA have no information as to what

amounts of the colors would have to be ingested by a human being in order to be dangerous to human health—that, in other words, F&DA have no idea whether or not the evidence as contained in the testimony of Dr. Voss, and in the various exhibits, indicates a possible danger to human health. All they claim to know is that they can make an animal sick by feeding it that color, if they force enough of the color down its throat. All they claim is that such farcical experiments demonstrate that the color is not "harmless" under any and every imaginable circumstance, hence must be outlawed.

This is probably the first time in the history of American government when any government department has prayed for the issuance of an order which would clothe them with well nigh limitless powers, while admitting that they have no evidence that indicates whether or not the actions they would take thereunder are necessary in the public interest —yet that is exactly what F&DA are contending for in the instant case.

[fol. 244] It requires but a casual examination of the feeding tests conducted by the pharmacologists of F&DA to disclose that Dr. Voss could not have testified that such experiments disclosed a possible danger to human health. As admitted by F&DA in their presentment to the Secretary, when requesting hearings on this subject, the peel of a Color Added orange contains but 4 parts of the color per million parts of the whole orange. The uncontradicted testimony of the Chief Chemist of the Florida Citrus Commission, shows that the juice from Color Added oranges contains 710/0 of 1 part of the color per million parts of juice, by weight.

The test in which F&DA pharamacologists fed color to dogs at the rate of 5 milligrams of color per kilogram of body weight (at which level of feeding the dogs suffered no injury) comes closest to, but is yet far from being, an indication of the amount of color that could safely be ingested by a human being by eating Color Added oranges or drinking the juice thereof.

It is the accepted rule of pharmacology that such tests should be translated into an equivalent dosage for a man weighing 70 kilograms, or approximately 154 pounds, it being assumed that if the animal so fed is not injured thereby, then the human being would not be injured by an

equivalent dosage. Such an equivalent dosage for such a man (5 milligrams of color per 70 kilograms of body weight) would call for that human being to ingest 350 milligrams of color per day. To ingest that amount of the color by eating Color Added oranges, he would be compelled, according to F&DA figures, to eat 437.5 oranges per day, peel and all, [fol. 245] for the test period—extending, in some cases, over six years. For human being to ingest 350 milligrams of the color by drinking the juice from Color Added oranges, that human being would have to drink 1,250 gallons of juice per day for the test period.

The above, ridiculous as it is when offered in support of a contention that the color so used might be harmful to human health, is but mildly laughable when compared to other tests which F&DA would have us believe indicate a possible danger to human health from the consumption of such food colors.

In other tests, dogs were fed 20 milligrams of color per kilogram of body weight, which would be equivalent to a dosage of 1400 milligrams for that human being weighing 70 kilograms, or 154 pounds, and to ingest that 1400 milligrams of color from eating Color Added oranges, that human being would have to eat, every day of the test period, 1,750 Color Added oranges, peel and all. To ingest that amount of color from drinking the juice of Color Added oranges, that person would have to drink 5,000 gallons of orange juice each day for the test period.

Other animans were fed 100 milligrams of color per day. The equivalent human dosage would be 7,000 milligrams of the color per day, for that 154 pound human being. To ingest that amount of color from eating Color Added oranges, that person would have to eat 8,750 oranges per day, peel and all, or drink 25,000 gallons of juice per day, for the test period..

Such is the preposterous nature of the tests which F&DA [fol. 246] has had the temerity to ask the Department and, eventually, the Courts, to say are sufficient to warrant the destruction of the citrus industries of Texas and Florida, through decertification of these colors.

As further supporting the allegations of Exception No. 2, attention is respectfully directed to the following:

(1) Re Finding of Fact 2: It is asserted that: "Because of advances in knowledge and techniques in the field of

pharmacology, the Food & Drug Administration has initiated new tests to explore more fully the toxicity of the certifiable coal-tar food colors. This involves the application of all techniques and procedures now considered necessary to assure proper evaluation. A number of these tests, with present-day techniques and procedures, have been conducted by the Division of Pharmacology of the Food and Drug Administration, using FD&C Orange No. 1, FD&C Orange No. 2, and FD&C Red No. 32."

The reason for that language is quite clear—exhaustive tests to determine both the immediate and cumulative ("chronic" is the new—and incorrect—word) toxicity of the color FD&C Red No. 32 had been run, by F&DA, over a period of five to six years, the result of such tests being a finding that such color had no appreciable toxicity, immediate or cumulative. Some means had to be found to discredit those tests, as justification for this new attack on the Color Added process. So we have this quoted language, obviously designed to mislead the uninformed into believing that the tests run from 1938 into 1944 were unreliable in the light of "advances in knowledge and techniques in the field of pharmacology."

[fol. 247] The cold, unadorned facts are these:

(a) That if there have been such "advances in knowledge and techniques in the field of pharmacology", F&DA has not used such advanced techniques in any of the tests reflected by the Exhibits put in evidence by F&DA. There is no single step followed in the tests run in 1952 and 1953, as shown by those Exhibits, that were not known and followed by research workers prior to the 1938-1944 tests.

(b) That, far from discrediting the tests run from 1938 to 1944, the tests run in 1952 and 1953 are, instead, discredited by the prior tests, because these later tests were by no means as comprehensive as the 1938-1944 feeding tests, nor does the analysis of the results of these later tests even approach the excellence of the analytical work done following the 1938-1944 tests, either in scope or as to fundamentals.

(2) Throughout the Findings of Fact filed by F&DA, we find references to loss of weight, coupled with references to diarrhea induced by such feeding. But nowhere in the Exhibits is there any reference to an inevitable fact—that much of this weight loss was due to malnutrition, due to the animals refusing food containing excessive amounts of color.

Instead, we are left—and intentionally do—to believe that every adverse effect noted is directly attributable to the consumption of the food color concerned.

(3) There are several references, in the said Findings of Fact, of tests for cancer, but no mention, anywhere that the results of such tests were negative.

[fol. 248] (4) In tests of this kind, the content of the "basic diet", and the amount thereof fed to these animals is of vital importance in appraising the results of such tests. This information is not given in either the Exhibits or Findings of Fact.

(5) There are repeated uses of the word "normal" in the Exhibits forming the basis for tests reported in Findings of Fact, but nowhere is this word defined, nor is it possible of definition.

(6) Reference is made to unfinished experiments, a curious practice in proceedings where a basic agricultural industry of two great States is thereby threatened with possible destruction.

(7) At pp. 8 and 9 of the Exhibits, reference is made to the gross pathology of formalin fix tissues, which references are not entirely accurate, as, for example, the reference to "rough surface" of livers. The meaning and signficance of the term is not stated. "Nutmeg livers" occur in many healthy animals. Parasites cause extensive damage to both livers and bile ducts.

The foregoing are a few of the many weaknesses and inaccuracies to be found in Exhibits and Findings of Fact which prompted and required this writer's petition for a reopening of these proceedings and the taking of full and complete evidence in the cause.

Obviously, in view of the prior decisions of our Courts that, before F&DA may prohibit the manufacture, transportation or sale of any properly labeled article of food [fol. 249] under an allegation that the same is or may be dangerous to health, it must be shown that such danger is real and apparent, not fanciful and imaginary, and that such article must be dangerous to human health in the amounts and under the conditions of ordinary and normal usage, each and every the contentions of F&DA must be overruled and the entire record of tests run, based on such travesties of alleged research as those hereinabove recited, must be held to be wholly meaningless and completely ir-

relevant insofar as concerns any relationship to human health, absent which relationship F&DA's attempted outlawing of these colors must be held to be an arbitrary and capricious abuse of delegated powers.

It is respectfully submitted that the Department of Health, Education and Welfare, which is charged with the duty and responsibility of policing the acts of its subordinate bureaus, may not lawfully uphold the fanciful contention of F&DA that the Congress of the United States solemnly enacted a statute which not only authorized, but instructed, that F&DA not only may, but must, outlaw any color, on the grounds that it is not "harmless", if the pharmacologists of F&DA can make any living creature ill by overfeeding and force feeding that creature with huge and fantastic quantities of such color under wholly unnatural conditions—as when a dog was fasted and then given 100 milligrams of the color, dissolved in oil and contained in a capsule, forced down the dog's throat, when its stomach was empty.

If that contention is not the ultimate in absurdity, certainly it is the penultimate, when it is considered that thus feeding pure proteins, or pure water, would likewise make [fol. 250] that animal ill, although those substances, when properly fed, are indispensable to life itself.

Exception No. 3: These proceedings were not initiated in good faith, nor have they been so conducted, by Food and Drug Administration.

Denied.

This writer fully appreciates the gravity of the allegations of this Exception but respectfully submits that, since it is clear on the record that there is no justification to be found, in law or facts, for the attempted outlawing of the Color Added process, by decertifying the food colors essential to the operation thereof, such allegations are not only proper but required, to the end that the Department of Health, Education and Welfare may take such action as may be necessary to prevent a recurrence of such capricious and arbitrary abuse of powers by one of its subordinate bureaus.

In further support of this Exception No. 3 we respectfully recite the following:

These proceedings constitute a renewal of attempts made by F&DA, in the years 1933-1938, to outlaw the Color Added process, and a faithless repudiation of agreements had with F&DA in 1938. The details of those attacks and of that agreement were heretofore recited in more detail.

We have already mentioned that the first word we had of the contemplated action related to the hearings already set for January 19, 1954, which data was accompanied by infor- [fol. 251] mation as to assurances given by F&DA (but not to this writer) that F&DA appreciated the necessity of the Color Added process to the citrus industries of Florida and Texas and that the proceedings thus instituted were in nowise directed thereagainst.

Then, on January 1st, 1954, just 16 days before said hearing was to be had, and, of course, far too late to make any adequate preparation to defend the Color Added process against the "sneak attack" thus launched, there appeared in the Tampa (Fla.) Tribune, under the by-line of Frederick Othman, a Washington columnist, a semi-humorous account of his troubles with some artificially colored sweet potatoes, in which he directly quoted Mr. George P. Larrick, then Assistant Commissioner of Food and Drugs, as saying:

"Larrick said I'd pounced on him at the exact psychological moment. Even as he examined the stains remaining on my hands, he said the administration's chemists were worrying about the colors going into *and in particular onto foods.*

"On January 19, he said, the administration would open formal hearings *on the subject of whether orange color with coal tar dyes.*

'The trouble is, he said, that some oranges, particularly in Florida, are still green colored when fully ripe. Citizens in other parts of the land refuse to buy 'em that color, so the packers have been dyeing them to make them look as sweet as they actually are. This has been perfectly legal. Each orange has borne the stamp: Artificially colored.

[fol. 252] "Some of these dyes used on oranges and in certain cakes, candies and soda pops" said Larrick, "were approved 40 years ago as non-injurious. Our chemists got to thinking a while back that perhaps they should take

another look. So they have been experimenting with animals, mostly rats, feeding them quantities of the colors mixed in their foods. They're gone about one-third way down the list of chemicals so far." (Italics mine.)

I am reliably informed that Mr. Larrick was asked about this statement that the upcoming hearings on January 19th were directed specifically to the question of "whether orange growers would be allowed to continue tinting their fruits orange color with coal tar dyes"; that Mr. Larrick did not directly deny the question, but stated that one couldn't go around denying what columnists write.

Thereupon, this writer wrote to Mr. Othman, asking verification or withdrawal of the stated quotation by Mr. Larrick, to which Mr. Othman replied, on January 20, 1954, as follows:

"DEAR MR. SCHELL:

"I appreciated the temperateness of your letter and I certainly can understand your feeling about the investigation, but I must report that my dispatch accurately quoted Mr. Larrick except for the fact that I leaned over backward in an attempt to be fair to the citrus industry.

"What Larrick actually said was that his chemists were worried in particular about the toxic effects upon rats of [fol. 253] three coal tar dyes used to color Florida oranges. The other dyes used in soft drinks, candies and cakes he had not considered so deleterious.

"Cordially yours, (Sgd.) Frederick C. Othman."

It would seem, from Mr. Othman's first paragraph, above, that Mr. Larrick's comments to him were not exactly partial to the citrus industries of Florida and Texas.

Please note that Mr. Larrick was concerned, particularly, with food colors going on to foods, and was, indeed, so particularly concerned as to the color on oranges that the hearing set for January 19th had as its principal, if not only, subject matter, the question of whether the Color Added process should be outlawed. Please note, also, the statement that the toxicity of some of the colors—and the context makes that reference applicable to the colors used in that process—had not been re-examined in 40 years. Compare that statement with the facts clear on the record that the

color FD&C Red No. 32 had been tested, only 8 years before, in a manner far more through, even exhaustive, than the tests just run in 1952-53; that both tests showed that, as Mr. Larrick now admits in his letter of February 7th, 1955, to Senator Smathers, the oranges colored by the Color Added process are entirely harmless for human consumption—then note that, despite this knowledge, all had by Mr. Larrick when he gave this interview to Mr. Othman, he was statedly concentrating his fire on the Color Added process. When these facts in the record are thus compared, an impartial judge cannot escape the profound conviction that Mr. Larrick's primary objective in these proceedings has been, from the very first, the destruction of the Color Added [fol. 254] process, his prior and subsequent protestations to the contrary notwithstanding, and that the allegation of a lack of good faith on the part of F&DA in the institution and prosecution thereof is well founded.

That conclusion is further supported and firmly established by the nature of the tests that were run to accomplish Mr. Larrick's purpose to destroy the Color Added process.

For example: Dr. Voss testified that the recheck on possible toxicity of coal tar food colors was prompted by a complaint that a child had been made ill by eating candy in which a water-soluble color, FD&C Orange No. 1, had been used at a rate that figures out 2500 parts of color per million parts of candy, by weight. (Oranges cannot be colored with FD&C Orange No. 1).

Such an isolated occurrence—and the record shows that to be the only complaint received on that or any other color—was undoubtedly the act of an ignorant person which could be—and doubtless was—corrected by administrative action. Would the fact that this writer is allergic to sulfa drugs, or that some other person had been given and overdoes thereof, be justification for banning the manufacture thereof? Surely, we are not being asked to accept, either as good law or common sense, the theory that if an article is possible of being misused then manufacture thereof must be prohibited.

We deem it significant that, despite the fact that the only complaint received by F&DA had to do with misuse of a [fol. 255] water-soluble color, Mr. Larrick said, according to Mr. Othman's letter, that he did not consider the colors

"used in soft drinks, candies and cakes" (i.e., the water-soluble colors) so deleterious.

Yet the veriest tyro knows that the water-soluble colors, if toxic at all, are far more dangerous than are the oil-soluble colors (which latter, only, are capable of coloring an orange).

These water-soluble colors are soluble in their entirety in the aqueous matter of every cell in the human body, comprising some 90% of the entire body weight, so that their capacity for evil, if toxic at all, is limitless.

The oil-soluble colors, on the other hand, are soluble only in the oleaginous constituents, the fatty matter, of the body, so that only a minute amount is absorbed—and it harmless to human health.

These facts, undoubtedly well known to Mr. Larrick, and his F&DA chemists, force us to doubt their good faith when they suggest, as they have done on several occasions, that the proponents of Color Added should "adapt" some of the water-soluble colors to the coloring of oranges.

There is a long list of certified food colors, both water-soluble and oil-soluble. It is extremely doubtful that there is a single food color on that list, whether water-soluble or oil-soluble, which would not make an animal ill if fed to such animal in the fantastic dosages used in testing FD&C Orange No. 2 and FD&C Red No. 32.

[fol. 256] Yet the record is significantly silent as to any recheck having been made of the toxicity of any of those food colors except FD&C Orange No. 1 (the water-soluble dye as to which the one lone complaint had been received) and the two oil-soluble colors that are indispensable to the operation of the Color Added process which Mr. Larrick identified as his primary target in his remarks to Mr. Othman.

Other factors which cannot but bring in question the good faith of F&DA in the institution and prosecution of these proceedings are:

(1) The misstatements and inaccuracies in the Findings of Fact filed in support of the proposed order, hereinbefore discussed.

(2) Statements made that the language of the statute compels the decertification of these colors, when, in fact,

Mr. Larrick's attempts are being made contrary to all law and good morals.

(3) The farcical nature, before discussed, of the tests run by F&DA pharmacologists, the very obvious purpose thereof being to prove that, if so misused, those colors will make an animal ill, not whether such colors pose a danger to human health when used under any imaginable amounts or conditions of normal usage.

(4) The reiteration of the incredibly distorted viewpoint that no color may remain on the certifiable list unless it be incapable of making any animal ill when fed in fantastic dosages under fantastic conditions—coupled with the asser- [fol. 257] tion that F&DA have no alternative to decertifying any color that will not meet a test under which even pure water could not qualify as being "harmless"—while at the same time giving a clean bill of health to oranges carrying a content of arsenate of lead that is 75% greater than the amount of harmless food color found in the peel of a Color Added orange.

(5) The querulous complaints of F&DA that the manufacturers are "dragging their feet" in the matter of formulation a less toxic color, while insisting upon moving Heaven and earth to establish a construction of the word "harmless" under which no food color could ever qualify for certification.

(6) The "weasel worded" sentence that ends Point (3) in the Statement of Fact, which language is clearly intended to be interpreted, by the uninformed, as a statement that a certain amount of experimental work with FD&C Orange No. 2 and FD&C Red No. 32 has been done on man, that adverse effects therefrom have been observed but not "definitely confirmed".

The fact is, of course, that F&DA have done no experimental work whatever with these two colors, with any human being. Why was there not used the forthright language set forth in the last sentence of the letter to Senator Smathers, dated February 7th, hereinbefore quoted? Could it be that the language used in the Findings of Fact were intended to mislead the Circuit Court of Appeals, should this cause finally come before that Court?

[fol. 258] (7) That when faced with an imminent disaster to the economy of two great States, arising out of what even F&DA must admit is, at best, a highly technical, strained and dubious interpretation of the word "harmless", we hear not one word from F&DA suggesting (or agreeing to) clarification of the Statute in such manner as to permit the continued use of a process which F&DA admits is completely harmless to human health and the record shows to be essential to the continued existence of the citrus industries of those States.

This record of reasons for inability to rely upon the good faith of F&DA in these proceedings could be extended indefinitely, but it is respectfully submitted that the foregoing should suffice to convince any impartial person that the real objective of F&DA, in these proceedings, is the outlawing of the Color Added process, their protestations to the contrary notwithstanding, and that the allegations of Exception No. 3 are well founded and proven on the record.

Conclusion

It is respectfully submitted that the allegations of the three Exceptions are fully sustained on the record, as pointed out in the brief.

It is further respectfully submitted and urged that (a) these proceedings should be dismissed instanter and those responsible therefor in F&DA should be disciplined for their irresponsible conduct in instituting the same, but if that be denied, then (b): These proceedings should be re-[fol. 259] opened so that the record may be made to reflect the true facts, to the end that justice and morality in Government may be served.

Respectfully submitted, Frank R. Schell.

Tampa, Florida, March 5, 1955.

Before Department of Health, Education And Welfare:

PETITION OF THE CERTIFIED COLOR INDUSTRY COMMITTEE TO REOPEN HEARINGS IN THE MATTER OF AMENDING SECTIONS FORMERLY NUMBERED §§ 135.1, 135.5 and 135.11 OF COLOR CERTIFICATION REGULATIONS.

1. Petitioner, The Certified Color Industry Committee, is a Committee representing a group of coal-tar color producers whose membership includes the producers of approximately 90% of the coal-tar color produced in the United States for use in food, drugs and cosmetics. Among such colors are the colors formerly listed (and herein referred to) as FD&C Orange No. 1, FD&C Orange No. 2 and FD&C Red No. 32.

2. By an order of the Secretary, dated November 10, 1955 (hereinafter sometimes called the Order) promulgated under Sections 406(b), 504, 604 and 701 of the Federal Food, Drug and Cosmetic Act, as amended (21 U.S.C. 301 et seq.), [fol. 260] and published at pages 8494 and 8495 of the Federal Register of November 16, 1955, § 135.3 of the Color Certification Regulations, which listed the coal-tar colors which the Secretary will certify as harmless and suitable for use in foods, drugs and cosmetics, was ordered to be amended so as to delete therefrom FD&C Orange No. 1, FD&C Orange No. 2 and FD&C Red No. 32. The Order, effective February 14, 1956, was made pursuant to Notice of Proposed Rule Making published at pages 9352 and 9353 of the Federal Register of December 30, 1954, and after public hearings held on January 19, 1954.

3. The Order contains findings to the effect that the internal administration to test animals of FD&C Orange No. 1, FD&C Orange No. 2 and FD&C Red No. 32, at various levels of administration, caused damage to the test animals.

4. The maximum extent to which each such color is used in foods under normal conditions of use as set forth in Exhibit A annexed hereto and made a part hereof, is substantially less than the lowest level of internal administration of such color found by the Order to have caused damage to test animals.

5. The coal-tar colors which are the subject of the Order have important functions in food, drugs and cosmetics and have been in use for many years. Their discontinuance would cause hardship to the American public and an important segment of American industry.

Wherefore, petitioner, The Certified Color Industry Com-
[fol. 261] mittee, without prejudice to the exceptions heretofore taken by it to the Order, respectfully petitions the Secretary to reopen hearings in the matter of amending Sections formerly numbered 135.3, 135.5 and 135.11 of the Color Certification Regulations, to take evidence as to the quantities of coal-tar colors FD&C Orange No. 1, FD&C Orange No. 2 and FD&C Red No. 32 used under normal conditions of use and by order to prescribe tolerances for such coal-tar colors within which they shall be continued to be certified as harmless and suitable for use in foods, drugs and cosmetics.

January 27, 1956.

Respectfully submitted, The Certified Color Industry Committee, By Michael F. Markel.

EXHIBIT "A" TO PETITION

Use of Coal-Tar Colors FD&C Orange No. 1, FD&C Orange No. 2 and FD&C Red No. 32 in Finished Foods Under Normal Conditions of use

Food	Color Content* (parts per million) Orange 1 (weighted average)	Orange 1 (maximum)	Orange 2 (maximum)	Red 32 (maximum)
Cakes, Cookies	19	163	—	42
Pies	31	236	—	—
Bread	—	1	—	—
Cheese (Processed, American, etc.)	—	—	60	15

[fol. 262]

Ice Cream	—	0.3	—	—
Frankfurters, Bolona, Spreads	39	90	—	—
Oranges—fresh whole fruit	—	—	—	7
Orange—fresh peel	—	—	—	34
Canned & Frosen Vegetables	—	5	—	—
Candy	31	300	—	—
Desserts & Puddings	27	291	—	—
Soft Drinks	—	10	—	—
Condiments, Soups, Pickles, Olives, Prepared Dishes	—	5	—	—

* Experimental Data.

Before Food and Drug Administration, Department of Health, Education, and Welfare.

ORDER DENYING PETITION OF THE CERTIFIED COLOR INDUSTRY COMMITTEE TO REOPEN HEARING.—Dated February 20, 1956

In the Matter of: Amending Sections 135.3, 135.5 and 135.11 of the Color Certification Regulations.

Docket No. FDC-60

The petition of the Certified Color Industry Committee [fol.263] to reopen the hearing for the purpose of taking additional evidence as to the "maximum extent to which each such color is used in foods under normal conditions of use" is hereby denied, for the following reasons:

1. Petitioner states that it is prepared to prove the maximum extent to which FD&C Red No. 32, FD&C Orange No. 1 and FD&C Orange No. 2 are used in foods under normal conditions of use; and that these amounts are substantially less than the lowest level of internal administration that caused harm to test animals.

2. Aside from the fact that the petition to reopen fails to controvert finding 8 which states that no safe level of administration to dogs of the color FD&C Red No. 32 was definitely established, it also fails to take into account the fact that man may be much more susceptible to harm from these colors than animals, as adverted to in finding 4. The general evidence which petitioner desires to produce would not change the order, if admitted, as explained below:

(a) Extent of Use of the Colors

The information contained in "Exhibit A" to the petition to reopen includes a list of finished foods in which it is alleged the colors FD&C Red No. 32, FD&C Orange No. 1, and FD&C Orange No. 2 are used in the amounts illustrated. The information in "Exhibit A" is more detailed than that adverted to in finding 10 supporting the final order, but it obviously is incomplete and no explanation is offered as to the meaning of "weighted

averages." Finding 10 would still be true if petitioner's [fol. 264] additional evidence as to amounts used were accepted. The evidence would show only the amounts of the colors used "under normal conditions of use" in the foods listed. The amounts occurring in other products would still be left to speculation, and there would be no limit upon the amounts of the colors which could be used under "abnormal conditions of use."

Since the close of the hearing, the Food and Drug Administration has investigated an incident in which popcorn colored with FD&C Red No. 32 caused severe illness to 196 children and adults. While this incident is not a matter of record, it serves to emphasize the point that colors listed for certification and certified as harmless by the Food and Drug Administration may be used in any quantity desired by food processors as well as manufacturers of drugs and cosmetics. Analysis of the popcorn referred to showed that it contained between 3,000 and 9,800 parts per million of FD&C Red No. 32. This figure is quite substantially larger than any found in "Exhibit A" which purports to show amounts of the colors used "under normal conditions of use."

The petition also fails to list the amounts of each color used in drug and cosmetic items, despite the fact that testimony that hearing establishes that the colors are used for coloring drugs and cosmetics (R. 102-106; 108).

The problem which would be encountered in attempting to determine the normal amounts of these colors which might be incorporated in the diet can be illustrated from the record in relation to FD&C Red No. 32. The witness, [fol. 265] Robert C. Evans, whose testimony appears at pages 91 to 98, testified that FD&C Red No. 32 is the principal color used in coloring oranges. He introduced Exhibit 7 which shows the number of oranges shipped from Florida for a number of years up to and including the 1952-53 season. Louis Gardner MacDowell, whose testimony appears at pages 98 to 106 testified that the average amount of dye contained on whole oranges was approximately six parts per million. A box of oranges weighs approximately 90 pounds. If we take the figures for the 1948 to 1949 season appearing on page 5 of Exhibit 7, we find the weight of the oranges colored that year

is approximately one billion eight million pounds. Assuming these oranges contained six parts per million of FD&C Red No. 32 that gives us a figure of approximately 11,000 pounds of this color which was used for coloring oranges. From the record of the hearing, this is the principal use of this color, yet the certification figures of the Food and Drug Administration show that for the past ten years the amounts of FD&C Red No. 32 certified have averaged 40,000 pounds. This leaves 29,000 pounds unaccounted for by the color estimated to be on the skin of oranges. The petition does not indicate that petitioner is prepared to show where this large amount of FD&C Red No. 32 would be used.

(b) Lack of Restraint on Quantities Used

Even if it were assumed that the figures presented in "Exhibit A" are accurate and complete at the present time, there is no way to guarantee that larger amounts of the colors will not be used in the future. The Federal Food, Drug, and Cosmetic Act makes no provision [fol. 266] for certifying poisonous coal-tar colors and then limiting the amounts of such certified colors which may be used in an effort to restrict the usage to safe levels. No standard or criteria have been established by the Congress whereby the Secretary may tolerate small amounts of poisonous colors in food, drugs, or cosmetics. In fact, an order establishing tolerances for a color which the Congress has stated in Sections 406(b), 504, and 604 of the Federal Food, Drug, and Cosmetic Act must be "harmless" would be contradictory by its very terms. Moreover, the Federal Food, Drug, and Cosmetic Act does not establish a standard or guide by which the Secretary could select some products, and exclude others, in allowing use of small amounts of coal-tar colors which are toxic. The only method by which such a result could be reached would be arbitrarily to state that the color or colors would be limited to some foods, drugs, or cosmetics and not to others. And neither the record nor the offer or additional testimony would establish any basis for choosing those products in which the colors should be allowed, and those in which their use would be prohibited.

(c) Proof of Harmlessness

The record of the hearing does not cantain adequate scientific data to provide a basis for determining at what levels of consumption the coal-tar colors FD&C Red No. 32, FD&C Orange No. 1, and FD&C Orange No. 2 may be safely used without injury to man. The pharmacological studies included in the record on the toxicity of these colors were designed to determine whether the colors could continue to be regarded as harmless, rather than to provide information on which a safe tolerance could [fols. 267-280] be set. The experiments show that the colors are not harmless. They do not provide sufficient data to establish exactly how toxic the materials are so that a tolerance could be fixed with confidence. The tests may be regarded as "unrealistic" only if their purpose is misunderstood. They were designed for the purpose of determining whether the colors under consideration could be regarded as harmless. They were the tests customarily employed by competent toxicologists for that purpose. So far as is known, there are no pharmacological or other data in existence which in any way contradicts the results of the Food and Drug Administration's studies shown in the record.

The fact that testimony may be available that no harmful or toxic reactions have been detected from the ingestion of the colors in quantities used would not be controlling. This Department's responsibility under the Federal Food, Drug, and Cosmetic Act is to certify only such coal-tar colors as are harmless, so that possible injury may be prevented.

Marion B. Folsom, Secretary of Health, Education, and Welfare.

Dated: Feb. 20, 1956.

[fol. 281] BEFORE DEPARTMENT OF HEALTH, EDUCATION AND WELFARE

Food and Drug Administration

FINAL ORDER OF THE SECRETARY OF HEALTH, EDUCATION AND WELFARE—November 10, 1955

Title 21—Food and Drugs

Chapter I—Food and Drug Administration, Department of Health, Education and Welfare

Part 135—Color Certification

Miscellaneous Amendments

In the Matter of Amending §§ 135.3, 135.5 and 135.11 of the Color Certification Regulations

Wednesday, November 16, 1955.

By virtue of the authority vested in the Secretary of Health, Education, and Welfare by the Federal Food, Drug, and Cosmetic Act (secs. 406 (b), 504, 604, 701; 52 Stat. 1049, 1052, 1055; 21 U. S. C. 346 (b), 354, 364, 371; 67 Stat. 18), upon the basis of substantial evidence received at the public hearing held pursuant to the notice published in the FEDERAL REGISTER on December 19, 1953 (18 F. R. 8600), and upon consideration of the exceptions filed to the proposed order published in the FEDERAL REGISTER on December 30, 1954 (19 F. R. 9352), which exceptions were allowed or not allowed as appears from notations on the exceptions on file with the Hearing Clerk, Department of Health, Education, and Welfare, Room 5440, Health, Education, and Welfare Building, 330 Independence Avenue SW., Washington 25, D. C., the following order is hereby promulgated.

Findings of Fact.[1] 1. after a hearing in 1939 concerning

[1] The citations following each finding of fact refer to the pages of the transcript of the testimony and the exhibits received in evidence at the hearing, except for citations to the FEDERAL REGISTER, where applicable.

regulations for the certification of coal-tar colors, the coal-tar color now listed as FD&C Orange No. 1 (monosodium salt of 4-*p*-sulfophenylazo-1-napthol) and the coal-tar color now listed as FD&C Orange No. 2 (1-*o*-tolylazo-2-napthol) were found to be harmless and suitable for use in food, drugs, and cosmetics. After another hearing in 1939, concerning amendment of the coal-tar color regulations, the coal-tar color now listed as FD&C Red No. 32 (1-xylylazo-2-napthol) was found to be harmless and suitable for use in food, drugs, and cosmetics. Accordingly, these three colors, among others, were listed with appropriate specifications of identity and quality in the coal-tar color regulations (21 C.F.R. 135.3) as certifiable for unrestricted use in foods, drugs, and cosmetics. (4 F. R. 1922, 1926, 1937, 3931, 3936, 3937; R. 46.)

2. Since that time the Food and Drug Administration has completed additional tests to explore more fully the toxicity of the certifiable coal-tar colors. A number of additional tests have been conducted by the Division of Pharmacology of the Food and Drug Administration, using FD&C Orange No. 1, FD&C Orange No. 2, and FD&C Red No. 32.

Tests that have been terminated are:

a. FD&C Orange No. 1:

i. Chronic feeding tests with rats on diets containing 0.1, 0.5, 1, and 2 percent.

ii. Chronic oral administration to dogs at doses of 5 milligrams per kilogram of body weight and 100 milligrams per kilogram of body weight.

iii. Cathartic tests in dogs, using single oral dose.

b. FD&C Orange No. 2:

i. Chronic or subacute feeding tests with rats on diets containing 0.01, 0.05, 0.1, 0.2, and 0.25 percent.

ii. Tests designed to determine carcinogenicity in rats, using weekly subcutaneous injections of approximately 5 milligrams. The test was inconclusive as to carcinogenicity and was discontinued after 8 injections. Three of the 18 test rats died on the dosage administered as compared to no deaths among the control rats.

iii. Carcinogenicity tests in mice, using subcutaneous implantation of 12.1 milligrams at intervals for 30 to 55 weeks. These tests produced no positive results.

iv. Chronic oral administration to 2 dogs at doses beginning at 100 milligrams per kilogram of body weight per day. The dosage was reduced successively to 20 milligrams and 5 milligrams in 1 dog, and to 20 milligrams in the other dog.

v. Chronic feeding tests in dogs at dietary levels of 0.2 percent and 0.04 percent.

vi. Cathartic tests in dogs, using single oral dose.

c. FD&C Red No. 32:

i. Chronic feeding tests with rats, on diets containing 0.1 percent.

ii. Subacute feeding tests with rats, on diets containing 0.25, 0.5, 1, and 2 percent.

iii. Chronic feeding tests with rats, on diets containing 0.1 percent and 0.25 percent.

iv. Carcinogenicity tests in rats, using weekly subcutaneous injections of approximately 5 milligrams to 10 milligrams. These tests were inconclusive as to carcinogenicity and were discontinued after 8 injections because 7 of the 18 test rats died or were sacrificed in extremis prior to the ninth injection. Similar toxic reactions were not encountered in the control rats. A second experiment, using weekly subcutaneous injections of approximately 1 milligram was also discontinued after 8 injections, because of deaths among the 18 test rats receiving FD&C Orange No. 2 in another part of this experiment.

v. Carcinogenicity tests in mice, using subcutaneous implantation of 10.8 milligrams at intervals for 35 weeks to 47 weeks showed no evidence of tumors.

vi. Chronic oral administration to dogs at doses of 5, 20, and 100 milligrams per kilogram of body weight per day.

vii. Chronic feeding tests in dogs at dietary levels of 0.04 percent and 0.2 percent.

viii. Cathartic tests in dogs, using single oral dose.

Tests of the three colors by external application to determine whether they are toxic when applied externally were being set up at the time of the hearing. (R. 8-78; Ex. 2, 3, 4.)

3. The tests with FD&C Orange No. 1 show that when taken internally at various levels of administration this color causes definite damage to various vital organs of the test animals, significant changes in body weight, and premature death.

This color caused the premature death of all rats on diets containing 2.0 percent of the test substance. Rats on a diet containing 1.0 percent of this substance showed marked retardation of growth, increased mortality, and chronic congestion and enlargement of the spleen. These same manifestations, to a lesser extent, were encountered in rats consuming a diet containing 0.5 percent of FD&C Orange No. 1. Dogs consuming 100 milligrams per kilogram of body weight per day of FD&C Orange No. 1 died in 26 months and 33 months. They had occasional diarrhea while alive and manifested terminal weight loss. Autopsy revealed congestion and atrophy of the liver attributable to the color. On a diet containing 1.0 percent of FD&C Orange No. 1, dogs exhibited chronic diarrhea. Rapid deterioration, and weight loss also occurred in 2 dogs. Autopsy revealed muscular dystrophic changes and testicular, prostatic, and uterine atrophy. These same manifestations occurred to a lesser extent in dogs on a diet containing 0.2 percent of FD&C Orange No. 1. A single dose of 100 milligrams to 200 milligrams of FD&C Orange No. 1 produced diarrhea in most dogs. Human volunteers who ate candy containing 0.07 per cent of FD&C Orange No. 1 exhibited diarrhea upon the ingestion of from one to eight pieces of the candy. Human volunteers taking 80 milligrams to 100 milligrams of the color in a single dose also experienced marked griping and diarrhea. (R. 14-22, 43-44; Ex. 2.)

4. Tests on rats at a level of 0.1 percent of the diet and on dogs at doses of 5 milligrams per kilogram of body weight per day did not produce any toxic effects attributable to FD&C Orange No. 1. However, these results must be contrasted with the diarrhea that resulted when human volunteers ate from one to eight pieces of candy containing 0.07 percent of FD&C Orange No. 1. This is particularly significant because man is shown to be more susceptible to the toxic effects of the color than are the test animals, and because the dogs having diarrhea (the symptom ob-

served also in man) showed damage to various vital organs after the chronic feeding tests. (R. 14, 16-18, 20-21, 43-44; Ex. 2.)

5. The tests with FD&C Orange No. 2 show that when taken internally at various levels of administration this color causes definite damage to various vital organs of the test animals, significant changes in body weight, and premature death.

FD&C Orange No. 2 caused severe growth retardation and increased mortality to rats on a diet containing 0.25 percent of the test substance. At 0.2 percent of the rats' diet, increased mortality and degeneration of the liver occurred. At a level of 0.1 percent of this substance in the diet, the rats exhibited marked growth retardation. At a level of 0.05 percent, autopsy revealed enlargement of the right side of the heart and, on microscopic examination, slight hypertrophy or hyperplasia of the cells in the liver. Approximately 5 milligrams per week given to rats by subcutaneous injection caused increased mortality and moderate growth retardation. Dogs consuming 100 milligrams per kilogram of body weight per day of FD&C Orange No. 2 lost weight or gained poorly. Twenty milligrams per kilogram of body weight per day caused one dog in the experiment to gain weight poorly. Five milligrams per kilogram of body weight per day apparently was tolerated by one dog without resultant injury. Dogs on a diet containing 0.2 percent of the test substance had diarrhea at the beginning of the experiment and exhibited [fol. 282] rapid deterioration and weight loss. Autopsy revealed atrophy of various vital organs caused by the color. At 0.04 percent of the diet, dogs gradually deteriorated and lost weight, and autopsy revealed atrophy of various vital organs. A single dose of 200 milligrams produced diarrhea in dogs. (R. 22-30; Ex. 3.)

6. FD&C Orange No. 2 caused damage to test animals at levels even lower than those at which damage was observed from FD&C Orange No. 1. The lowest level at which demonstrable harm to test animals was observed from FD&C Orange No. 2 was 0.04 percent of the diet of dogs. The lowest level at which FD&C Orange No. 1 caused demonstrable damage was 0.2 percent in the diet of dogs and 0.07 per cent when ingested by man in a single dose. (R. 18-19, 20-21, 28, 43-44, 67-68; Ex. 2, 3.)

7. The tests with FD&C Red No. 32 show that when taken internally at various levels of administration this color caused definite damage to various vital organs of the test animals, significant changes in body weight, and premature death.

When this color was fed to rats at a level of 2.0 percent of the diet, all the rats died within a week. At a 1.0 percent level, death occurred within 12 days. At 0.5 percent most of the rats died within 26 days. At 0.25 percent approximately half of the rats died within 3 months. All of the rats at this level showed marked growth retardation and anemia. Autopsy revealed moderate to marked liver damage. Similar but less severe results were obtained with rats on a diet containing 0.1 percent of FD&C Red No. 32. In addition to liver damage, however, autopsy also revealed enlargement of the right side of the heart in this latter group. Subcutaneous injection of approximately 10 milligrams per week caused death within 8 weeks to nearly half of the rats on the experiment. These rats exhibited anemia, hemorrhage and reduction in the size of the liver. Dogs taking 100 milligrams per kilogram of body weight per day showed moderate weight loss. A level of 0.2 percent of FD&C Red No. 32 in the diet of dogs caused rapid deterioration and weight loss and sporadic diarrhea; 0.04 per cent caused gradual deterioration and weight loss, sporadic diarrhea, moderate atrophy of vital organs, and muscular dystrophic changes; 0.01 percent in the diet caused weight loss and the death of one out of 4 dogs. A single oral dose of 100 milligrams or 200 milligrams caused diarrhea in the majority of the dogs tested. (R. 30-38; Ex. 4.)

8. The lowest level at which FD&C Red No. 32 showed damage to test animals was at 0.01 per cent of the diet of dogs. This was the lowest level at which the color was administered in the diet and, based upon the conversion figures appearing in the record, it is a lower dosage than the level of 5 milligrams per kilogram which produced no apparent effect on other dogs. Thus, no safe level of adminstration to dogs was definitely established. (R. 35-37, 40-42; Ex. 4).

9. The only known episode of illness in man was caused by FD&C Orange No. 1. It is the least toxic of the three

colors. The fact that no human ailment has been attributed to the other colors means little, because few people know what colors they are eating and the delayed toxic effects of the colors, as evidenced by the test animals, involve damage to vital organs and processes that would not have been attributed to the colors even if caused by them.

10. There was no evidence on which findings could be made concerning how much of the three colors is likely to be ingested by man from his food, drugs and cosmetics. Some interested persons, taking their own products, attempted to show that the amounts ingested would be small to the point of insignificance. But those contentions leave aside the occurrence of the colors in the products of others, as well as the fact that upon certification of a color the Department has no means of controlling the amounts of colors used in a variety of food, drugs, and cosmetics. Nor is there authority to limit a color, once certified, to a single food—for example, FD&C Red No. 32 for use in color-added oranges. (R. 20-21, 67-68, 98-108; Ex. 8.)

11. The coal-tar colors listed in the regulations as FD&C Orange No. 1, FD&C Orange No. 2, and FD&C Red No. 32 may be used at present in externally applied drugs and cosmetics as well as in products for internal consumption. Tests designed to examine the toxicity of these colors, when used externally, are not complete. (R. 46-48, 63-65.)

12. Modification of the coal-tar color certification regulations (21 CFR 135.11 (d)(2)) to eliminate the requirement for 3 months' written notice of change in composition of a coal-tar color mixture will facilitate the marketing of substitute mixtures and reduce confusion that may result from the deletion of a straight color from the listings at 21 CFR 135.3, 135.4, and 135.5. (R. 88, 89.)

Conclusions. 1. Based upon the above findings, the coal-tar colors FD&C Orange No. 1 (monosodium salt of 4-*p*-sulfophenylazo-1-napthol), FD&C Orange No. 2 (1-*o*-tolylazo-2-naphthol) and FD&C Red No. 32 (1-xylylazo-2-naphthol), described in the coal-tar regulations (21 CFR 135.3) are not harmless and suitable for use in coloring food or for use in coloring drugs or cosmetics intended for other than external application.

2. Sections 406 (b), 504, and 604 of the Federal Food,

Drug, and Cosmetic Act (21 U. S. C. 346 (b), 354, and 364) provide for the listing of coal-tar colors that are harmless and suitable for use in food, drugs, and cosmetics. The act does not provide any method for listing toxic colors for specific food, drug, or cosmetic uses so as to limit their total use to small enough amounts that the toxcity might be disregarded. Under the statute a toxic color cannot be classified as a harmless color.

3. While a safe level of administration to test animals is disclosed by the record in the case of FD&C Orange No. 1, the record also discloses that that color has adverse effects upon man at a level well below the safe level of administration to test animals. The safe level of administration of FD&C Orange No. 2 to test animals is well below the level at which FD&C Orange No. 1 was found safe to test animals. It is, therefore, even more toxic than FD&C Orange No. 1. No safe level of administration was found even in test animals for FD&C Red No. 32.

4. The coal-tar colors FD&C Orange No. 1, FD&C Orange No. 2, and FD&C Red No. 32 are not harmless and suitable for use within the meaning of sections 406 (b), 504, and 604 of the Federal Food, Drug, and Cosmetic Act in coloring food or in coloring drugs or cosmetics intended for other than external application.

5. The coal-tar colors FD&C Orange No. 1, FD&C Orange No. 2, and FD&C Red No. 32 should be deleted from the listing at 21 CFR 135.3, since the Secretary cannot continue to list these colors as colors that the Food and Drug Administration will certify as harmless and suitable for unrestricted use in coloring food or in coloring drugs and cosmetics intended for other than external application.

6. Colors conforming to the present regulations and specifications for FD&C Orange No. 1, FD&C Orange No. 2, and FD&C Red No. 32 should be added to the listing at 21 CFR 135.5, for use in coloring externally applied drugs and cosmetics only.

7. The provisions of 21 CFR 135.11 (d) (2) requiring 3 months' written notice of a change in the composition of a coal-tar color mixture should be waived when such change is made necessary by deletion of one or more straight colors from the listings at 21 CFR 135.3, 135.4, or 135.5.

Therefore, it is ordered, That Part 135—Color Certification, be amended in the following respects:

1. In § 135.3 (a), delete the colors FD&C Orange No. 1, FD&C Orange No. 2, and FD&C Red No. 32.

2. Add the following to § 135.5 (a):

Ext D&C Orange No. 3

Specifications

Monosodium salt of 4-*p*-sulfophenylazo-1-naphthol.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water-insoluble matter, not more than 0.3 percent.

Ether extracts, not more than 0.2 percent.

α-Naphthol, not more than 0.1 percent.

Chlorides and sulfates of sodium, not more than 4.0 percent.

Mixed oxides, not more than 1.0 percent.

Orange II, not more than 5.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 85.0 percent.

Ext D&C Orange No. 4

Specifications

1-*o*-Tolylazo-2-naphthol.

Volatile matter (at 100° C.), not more than 0.5 percent.

sulfated ash, not more than 0.3 percent.

Water-soluble matter, not more than 0.3 percent.

Matter insoluble in carbon tetrachloride, not more than 0.5 percent.

o-Toluidine, not more than 0.05 percent.

β-Napthol, not more than 0.05 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 98.0 percent.

Melting point, not less than 128.0° C.

[fol. 283] Wednesday, November 16, 1955.

EXT. D&C RED No. 14

Specifications

1—Zylylazo-2-napthol.

Volatile matter (at 100° C.), not more than 0.5 percent.

Sulfated ash, not more than 0.3 percent.

Water-soluble matter, not more than 0.3 percent.

Matter insoluble in carbon tetrachloride, not more than 0.5 percent.

Xylidene, not more than 0.1 percent.

6-Naphthol, not more than 0.05 percent.

m-Xylidine in xylidine obtained by reduction of the dye not more than 30.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 97.0 percent.

Boiling range of xylidine, obtained by reduction of the dye, 95 percent between 212°-232° C.

3. Amend § 135.11 (d) (2) so that, as amended, it willl read as follows:

§ 135.11 *Labeling.* • • •

(d) • • •

(2) The name of such mixture is the same as or simulates the name of a previously certified batch of a mixture containing a different substance, or a different percentage of a pure dye; but this provision shall not apply if:

(i) The person who requests certification of such batch is the owner of such name and has given 3 months' written notice to the Food and Drug Administration specifying the change to be made in the composition of such mixture; or

(ii) Such change results from removal of a color from the listings in §§ 135.3, 135.4, and 135.5.

Effective date. This order shall be effective 90 days after publication in the Federal Register.

(Sec. 701, 52 Stat. 1055; 21 U. S. C. 371)

Dated: November 10, 1955.

M. B. Folsom, Secretary. (Seal.)

[F. R. Doc. 55-9209; Filed, Nov. 15, 1955; 8:49 a. m.]

[fol. 284] MINUTE ENTRY OF ARGUMENT AND SUBMISSION IN CASE No. 15934—May 8, 1957

(Omitted in Printing)

[fol. 285] MINUTE ENTRY OF ARGUMENT AND SUBMISSION IN CASE No. 15948—May 8, 1957

(Omitted in Printing)

[fol. 286] IN THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

No. 15934

FLORIDA CITRUS EXCHANGE, et al., Appellants,

versus

M. B. FOLSOM, Secretary of the Department of Health, Education and Welfare, Appellee

No. 15948

FRANK R. SCHELL, Appellant,

versus

M. B. FOLSOM, Secretary of the Department of Health, Education and Welfare, Appellee

On Petitions for Review of an Order of the Secretary of Health, Education and Welfare

Before Hutcheson, Chief Judge, and Jones and Brown, Circuit Judges

OPINION—July 12, 1957

JONES, Circuit Judge: In the nineteen-thirties growers and packers of oranges in Florida and Texas began the [fol. 287] practice of adding color to the rind of oranges. Early oranges, maturing during warm weather, will ripen

to full maturity with the skin still green in color. Oranges maturing in the late winter or spring may fully ripen and undergo a "regreening" of the rind. The orange-purchasing public requires an orange-colored orange and will not accept those with green rinds. Representatives of a substantial number of those engaged in the growing and marketing of citrus fruits in the two states assert that severe economic reverses would result from a prohibition of adding color to the fruit; indeed it has been asserted that the future of the orange industry of these states is dependent upon the continued coloring of its product.

In 1938 the Congress enacted the present Federal Food, Drug and Cosmetic Act. 52 Stat. 1040; 21 U.S.C.A. §§ 301-392. The adulteration of food in interstate commerce and the introduction of adulterated food into interstate commerce were prohibited. 21 U.S.C.A. § 331. Congressional standards for determining when food would be deemed adulterated were set up.[1] Provisions for tolerances of poi-

[1] "A food shall be deemed to be adulterated—

"(a) (1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health or (2) if it bears or contains any added poisonous or added deleterious substance which is unsafe within the meaning of Section 406; or (3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or (4) if it has been prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or (5) if it is, in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter; or (6) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health.

"(b) (1) If any valuable constituent has been in whole or in part omitted or abstracted therefrom; or (2) if any substance has been substituted wholly or in part therefor;

[fol. 288] sonous and deleterious substances were included.[2]

The Secretary of Agriculture, to whom the administration of the Act was originally committed, issued regulations on May 4, 1939, effective May 9, 1939, governing the

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or (3) if damage or inferiority has been concealed in any manner; or (4) if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.

"(c) If it bears or contains a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by Section 406; PROVIDED, That this paragraph shall not apply to citrus fruit bearing or containing a coal-tar color if application for listing of such color has been made under this Act and such application has not been acted on by the Secretary, if such color was commonly used prior to the enactment of this Act for the purpose of coloring citrus fruit.

* * * * * * *

52 Stat. 1046, § 402, 1 U.S.C.A. § 342.

[2] "(a) Any poisonous or deleterious substance added to any food, except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice shall be deemed to be unsafe for purposes of the application of clause (2) of section 402 (a); but when such substance is so required or cannot be so avoided, the Secretary shall promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health, and any quantity exceeding the limits so fixed shall also be deemed to be unsafe for purposes of the application of clause (2) of section 402 (a). While such a regulation is in effect limiting the quantity of any such substance in the case of any food, such food shall not, by reason of bearing or containing any added amount of such substance, be considered to be adulterated within the meaning of clause (1) of section 402(a). In determining the quantity of such added substance to be tolerated in or on different articles of food the Secretary shall take into account the extent to which the use of such substance is required or cannot be avoided in the production of each such article, and the other ways in which the con-

[fol. 289] listing of coal-tar colors.[3] Among those eligible for certification were listed F D & C Orange No. 1 F D & C Orange No. 2, and F D & C Red No. 32.[4] In 1954 the Secretary of Health, Education and Welfare, succeeded to the administration of the Act in the place originally held by the Secretary of Agriculture.[5] The Secretary reached the conclusion that the three colors are not "harmless" as that word is used in Section 406(b) of the Act. 21 U.S.C.A. §346(b). An order promulgating a further regulation[6] was issued by which the three colors were deleted from the list approved for certification for use in foods and in drugs to be taken internally. By Section 701 (f) of the Act,[7] any person who will be adversely affected by an order of the Secretary may file a petition for review with the court of appeals for the circuit wherein such person resides. Petitions for review were filed in threee circuits. In the Seventh Circuit the proceeding for review was dismissed. In the Second Circuit, by a decision which we shall hereafter discuss, the Secretary's order was affirmed. *Certified Color Industry Committee v. Secretary of Health, Education and Welfare*, 2 Cir. 1956, 236 F. 2d 866. Two petitions for review have been filed in this Circuit, one by Florida Citrus Exchange and others, orange growers and packers of Florida and Texas, and the other by Frank R. Schell, the holder of patents on the process for the coloring of citrus [fol. 290] fruits with Orange 2 and Red 32. The two proceedings for review in this Court have been consolidated.

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umer may be affected by the same or other poisonous or deleterious substances.

"(b) The Secretary shall promulgate regulations providing for the listing of coal-tar colors which are harmless and suitable for use in food and for the certification of batches of such colors, with or without harmless diluents." 52 Stat. 1049, § 406, 21 U.S.C.A., § 346.

[3] 4 F.R. 1935, 1 C.F.R. 1939 Supp. 1214 et seq.

[4] 4 F. R. 3936, 1 C.F.R. 1939 Supp. 1214, 1218.

[5] Reorganization Plan No. 1 of 1953, 67 Stat. 631, 18 F. R. 2053; 67 Stat. 18, 5 U.S.C.A. § 623.

[6] 20 F. R. 8492.

[7] 21 U.S.C.A. §371 (f).

Red 32 is the only one of the three colors with which we are concerned in this proceeding.

The three colors were on the original list, prepared in 1939, of coal-tar colors available for certification. Some of the coal-tar colors on the list became suspect as toxic and possibly carcinogenic. This prompted further investigation which culminated in the hearings which formed the bases of the order which we here review. At the hearing evidence was introduced that rats did not survive a diet of 1000 parts per million of Red 32. A dog fed 100 parts per million of Red 32 sickened and ultimately died. This was the lowest percentage tested of Red 32. Evidence was introduced at the hearing which showed that Red 32, when used for coloring oranges penetrated the skin for a depth of about 1/1000 of an inch; that peel of the colored orange had from 17.63 to 34.26 parts per million of color; candied orange peel had 7.4 parts per million of color; orange marmalade analyzed 1.8 parts per million of color; and the squeezed juice of colored oranges had a color content range of from 4/100 of one part per million to 7/100 of one part per million. A spokesman for the entire coal-tar color industry stated that the sale of Red 32 had been discontinued for any purpose except the coloring of oranges. The principal witness for the Secretary was Dr. Vos, Assistant Chief of the Division of Pharmacology of the Food and Drug Administration. He reviewed the tests made upon animals. He testified that on the basis of the experiments and his education and experience he was of the opinion that Red [fol. 291] 32 was not a "harmless coal-tar color". On cross-examination he stated that he used the word "harmless" in the absolute sense that the color was capable of producing harm. This was developed by his saying that bad results might follow the taking of two or three ounces of salt but, salt being essential, it would not be regarded as harmful. He had no evidence as to whether the color would produce harmful effects at ordinary levels of use, although he gave an affirmative answer to the question "Aren't the amount and method of proposed use of a material necessary data for deciding whether the material is harmless for the use intended?"

The order of the Secretary which we here review made findings of fact based upon the evidence of the tests of

which Dr. Vos testified. At the conclusion of nine paragraphs of specific findings as to the effects of the various quantities of the colors given to animals with mention of one episode of illness resulting to man from eating popcorn colored with Orange 1 where the percentage level did not appear, the Secretary stated:

> "There was no evidence on which findings could be made concerning how much of the three colors is likely to be ingested by man from his food, drugs, and cosmetics. Some interested persons, taking their own products, attempted to show that the amounts ingested would be small to the point of insignificance. But those contentions leave aside the occurrence of the colors in the products of others, as well as the fact that upon certification of a color the Department has no means of controlling the amounts of colors used in a variety of foods, drugs, and cosmetics. Nor is there authority [fol. 292] to limit a color, once certified, to a single food—for example, FD&C Red No. 32 for use in color-added oranges."

By the order it was determined that Red 32 and the other two suspect coal-tar colors were not harmless and suitable for use in food, drugs and cosmetics and these colors were deleted from the approved list. The legal theory upon which the order was based is found in paragraph 2 of the Secretary's conclusions where it was held:

> "Sections 406 (b), 504, and 604 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346 (b), 354, and 364) provide for the listing of coal-tar colors that are harmless and suitable for use in food, drugs, and cosmetics. The act does not provide any method for listing toxic colors for specific food, drug, or cosmetic uses so as to limit their total use to small enough amounts that the toxicity might be disregarded. Under the statute a toxic color cannot be classified as a harmless color."

The primary attack of the petitioners is upon the correctness of the principle as stated in the foregoing quotation.

When the order of the Secretary was entered an effort was made to procure an amendment to the Act to require the Secretary to permit Red 32 to be used in coloring oranges until a more acceptable color should be made available. The amendment as originally offered was opposed by the Department of Health, Education and Welfare. The measure, as finally agreed upon by its proponents and representatives of the Department, amended [fol. 293] Section 402 (c) of the Act by adding thereto the following:

> "Provided further, That this paragraph shall not apply to oranges meeting minimum maturity standards established by or under the laws of the States in which the oranges were grown and not intended for processing (other than oranges designated by the trade as 'packing house elimination'), the skins of which have been colored at any time prior to March 1, 1959, with the coal-tar color certified prior to the enactment of this proviso as F.D.&C. Red 32, or certified after such enactment as External D.& C. Red 14 in accordance with section 21, Code of Federal Regulations, part 9: And provided further, That the preceding proviso shall have no further effect if prior to March 1, 1959, another coal-tar color suitable for coloring oranges is listed under section 406". 70 Stat. 512; 21 U.S.C.A. § 342 (c).

While this amendment was pending before the House of Representatives where it had its origin,[8] a committee hearing was held. Before the committee was a letter from the Secretary of Health, Education and Welfare where it was stated that the evidence so far available does not establish what the lowest safe dosage of Red 32 would be to test animals, neither does it establish a likelihood of injury to man from the use of the color on the exterior of oranges at the levels of use involved. The studies, said the Secretary, were not designed to determine whether a safe tolerance could be established for a single food, such as oranges, so that the amounts that might be consumed as color on the exterior surface of oranges would pose no

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[8] H. R. 7732.

[fol. 294] undue risk.[9] The Commissioner of Food and Drugs appeared and gave a statement at the hearing similar to and in some respects amplifying those contained in the Secretary's letter. He reiterated that the tests made were not designed to learn the effect upon human beings of the minute quantities of the color that might be ingested by its use as an orange coloring. He stated that although the color had been used on oranges since in the early 1930's, no evidence has been found that injury has resulted from the consumption of oranges so colored. This use, said the Commissioner, presented a strong equity for conducting tests. He stated, as did the Secretary, the view of the department that if the color was "harmful" its use must be prohibited and that no tolerances could be fixed.[10] Among the purposes of the amendment, as explained in the report of the Committee of the House of Representatives, was the allowing of time for further exploration of the toxicity of Red 32. In the report it was stated that the practice of coloring the skins of oranges has become an economic necessity for a major segment of the orange industry.[11] In the report of the Senate Committee on Labor and Public Welfare, to whom the bill was referred, the same conclusions were reached.[12] On this factual situation and background we review the order of the Secretary.

The petitioners list twelve specifications of error upon which they ground their attack upon the Secretary's order. The basic and underlying contention of the petitioners is [fol. 295] that the Secretary has erred in construing "harmless", as used in Section 406 (b) of the Act, in an absolute rather than in a relative sense. If the position of the Secretary is correct, he has no choice but to refuse to permit a coal-tar color to be used in food in minute, safe and harmless quantities if, when used in much larger quantities it would or might be injurious or dangerous to

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[9] Hearing before a Subcommittee of the Committee on Interstate and Foreign Commerce House of Representatives, 84th Cong., 2d Sess. on H.R. 7732, pp. 2 and 3.

[10] Hearing, supra, pp. 17 and 18.

[11] H. R. Rep. No. 1982, 84th Cong., 2d Sess.

[12] S. Rep. No. 2391, 84th Cong. 2d Ses.

health. If the position of the Secretary is correct he has no power to permit a particular coal-tar color to be used for a specific and restricted purpose even though, when so used, it would not be injurious or dangerous to health.

The Secretary has urged that the questions presented for our review are the identical questions which were decided by the Second Circuit in *The Certified Color Industry Committee v. The Secretary of Health, Education and Welfare, supra,* and that we should follow that decision unless we are convinced it was clearly wrong. Where an identical issue is presented and no different principle is involved, the decision of another court of appeals is entitled to great weight and affords persuasive argument.[13] Although the appeal in the Certified Color Industry case was from the same order and was upon the same record as the case before us, the identical issue is not presented and a different principle is involved. In the Second Circuit case three coal-tar colors were involved and the uses were all inclusive. The difference was recognized by the Court of Appeals for the Second Circuit. In its opinion it is said:

> "Thus the problem is far different from the one presented recently to Congress when the act was amended [fol. 296] to permit the use of Red 32 on orange skins not intended for processing. With only one product contaminated it was not too difficult to argue that such small amounts were involved that a man would have to drink 5000 gallons of orange juice a day before experiencing any adverse effects." 236 F. 2d 871.

The problem we consider is not that which the Second Circuit had and the decision there is, as we hope to show, not in conflict with what we decide here.

In a brief filed with us by amicus curiae, he quotes from a letter to him from the Food and Drug Administration where it was said;

> "Let me say at the outset that this Administration is in agreement with your conclusion that the use of

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[13] Sokol Brothers Furniture Co. v. Commissioner of Internal Revenue, 5 Cir. 1950, 185 F. 2d 222, reh. den. 185 F. 2d 677, cert. den. 340 U. S. 952, 71 S. Ct. 571, 95 L. Ed. 686.

added color is inherently deceptive and is contrary to the interests of both consumers and producers."

This letter is not in the record and would not be the subject of comment by us but for a suggestion that it evidences a hostile and prejudiced attitude of the Food and Drug Administration. We think the record shows the contrary to be the case. It is shown that all oranges to which color is added are so marked and that immature fruit is not colored. The record reflects a departmental attitude of fairness and objectivity, and discloses that the ill-advised statement of the writer of the letter does not express the view of the Secretary or of the department.

[fol. 297]. It has been contended that the officers charged with the administration of the Act had, from the time the Act was passed until the time of the investigation which culminated in the hearings and in the order we here review, construed the Act as permitting, if not requiring, the fixing of tolerance for harmless uses of Red 32. Such administrative construction should be persuasive, so we are told, if not binding as an administrative construction of an ambiguous provision. The Secretary, on the other hand, asserts that the administrative interpretation has not altered, and that the change of position resulted from the different findings of fact required by the recent investigations and experiments. We need not pursue this inquiry. An administrative construction which is clearly erroneous is not binding on the administrative agency nor is it persuasive in judicial proceedings,[14] and this should be particularly true where the purpose of the Act is to protect the health of the public.[15] The doctrine of giving weight to an administrative construction of a statute does not apply to an administrative determination of the administrator's statutory powers.[16] This, in essence, is one of the questions before us.

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[14] 82 C.J.S. 771, Statutes § 359 b.

[15] The purposes of the Act are discussed infra.

[16] Stark v. Brannan, D.C.D.C. 1949, 82 F. Supp. 614, aff. 87 U.S.App. D.C. 388, 185 F.2d 871, aff. 342 U.S. 451, 72 S. Ct. 433, 96 L. Ed. 497.

The decision we are to make is whether the Secretary of Health, Education and Welfare is required or permitted to determine if there is a minimum quantity of the coal-tar color designated as F D & C Red No. 32 which can be used in adding color to the skins of mature oranges without danger of impairing the health of those who consume [fol. 298] such oranges; and if so required or permitted, and if it be determined that there is such minimum, should the Secretary list and certify such color for such use. In the construction of statutes courts will look to the entire act and to its objects and policy.[17] Results which are incongruous [18] or absurd [19] are to be avoided. Where a particular construction of a statute will occasion great inconvenience or produce inequality and injustice, that view is to be avoided if another and more reasonable interpretation is present in the statute.[20] In the construction of a legislative measure, statutes in pari materia, amendatory acts, and their legislative history may be examined.[21] These rules are the primary guides to our solution of the problem before us.

In the leading and often cited Lexington Mill case [22] the Supreme Court declares the purpose of the Act, saying:

> "The statute upon its face shows, that the primary purpose of Congress was to prevent injury to the

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[17] Mastro Plastics Corporation v. National Labor Relations Board, 350 U.S. 270, 76 S. Ct. 349, 100 L.Ed. 309, National Labor Relations Board v. Lion Oil Co., et al, 352 U.S. 282, 77 S. Ct. —, 1 L. Ed. 2d 331; United States v. Witkovich, 353 U. S. 194, 77 S. Ct. —, 1 L. Ed. 2d 765.

[18] National Labor Relations Board v. Lion Oil Co., et al, supra.

[19] United States v. American Trucking Associations, Inc., 310 U.S. 534, 60 S. Ct. 1059, 84 L. Ed. 1345; Fulford v. Forman, 5 Cir. 1957, — R. 2d —.

[20] Knowlton v. Moore, 178 U. S. 41, 20 S. Ct. 747, 44 L. Ed. 969.

[21] United States v. Freeman, 44 U. S. (3 How.) 556, 11 L. Ed. 724.

[22] United States v. Lexington Mill & Elevator Co., 232 U. S. 399, 34 S. Ct. 337, 58 L. Ed. 658.

public health by the sale and transportation in interstate commerce of misbranded and adulterated foods. • • • As against adulteration, the statute was in- [fol. 299] tended to protect the public health from possible injury by adding to articles of food consumption poisonous and deleterious substances which might render such articles injurious to the health of consumers." 332 U. S. 409.

The purpose to protect the public health is an important aim of the statute,[23] and touches phases of the lives and health of people which are largely beyond self-protection.[24]

We are here reviewing the order of the Secretary only with respect to the coal-tar color F D & C Red No. 32 as used in the coloring of the skins of oranges. If there be other like situations, then of course that which we hold will be applicable to them. We are not confronted with the broad questions which were before the Second Circuit in the Certified Color Industry case, *supra*.

In some of the cases[25] the de minimis doctrine has been recognized as applicable or has been applied in adulterated food cases. The contentions of the petitioners suggest that they regard the doctrine applicable here. Neither the Secretary's findings nor the evidence on which they were [fol. 300] based calls for any consideration of the doctrine upon the record before us.

The words "harm", "harmful", and "harmless" are terms of relation. In this sense they resemble "wrong"

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[23] United States v. Coca-Cola Co., 241 U. S. 265, 36 S. Ct. 573, 60 L. Ed. 995.

[24] United States v. Dotterweich, 320 U. S. 277, 64 S. Ct. 134, 88 L. Ed. 48, reh. den. 320 U. S. 815, 64 S. Ct. 367, 88 L. Ed. 492; 62 Cases of Jam v. United States, 340 U. S. 593, 71 S. Ct. 515, 95 L. Ed. 566.

[25] United States v. 449 Cases, 2 Cir. 1954, 212 F. 2d 567, 45 A.L.R. 2d 846; 338 Cartons v. United States, 4 Cir. 1947, 165 F. 2d 728; A. O. Andersen & Co. v. United States, 9 Cir. 1922, 284 F. 542; United States v. 298 Cases, D.C.Ore. 1949, 88 F. Supp. 450; United States v. 184 Barrels, D.C.E.D. Wis. 1943, 53 F. Supp. 652; United States v. 133 Cases, D.C.E.D. Pa. 1938, 22 F. Supp. 515.

and "wrongful".[26] Red 32 is harmless, i. e. not harmful, to all persons under the protection of the Act while it remains in the vat or the vial. An injury must occur before harm results. The color Red 32 becomes harmful, i.e. not harmless, when it is consumed, and then only if consumed in such quantity that injury or harm might result. If there can be a use of the color in such small quantities that it can be consumed without risk or injury or harm then, in such quantities, it is harmless. A person is as unharmed after consuming a minute harmless quantity of Red 32 (if such there be) as he would be had he consumed none of it.

In *United States v. Lexington Mill & Elevator Co., supra,* the Supreme Court reviewed the condemnation of a lot of flour to which had been added a poisonous ingredient but in a quantity so small that the health of a consumer could not be thereby injured. The statute then provided that an article of food should be deemed to be adulterated if it "contain any added poisonous or other added deleterious ingredient which may render such article injurious to health". It was contended there, as it is contended here, that it is the character—not the quantity—of the added substance which is to determine the case. This contention was rejected. The Court said:

> "If it cannot by any possibility, when the facts are reasonably considered, injure the health of any con- [fol. 301] sumer, such flour, though having a small addition of poisonous or deleterious ingredients, may not be condemned under the act." 232 U.S. 411.

As in the Lexington Mill case, it was held in the Seventh Circuit that "injurious" is a relative rather than an absolute term. *W. B. Wood Mfg. Co. v. United States,* 7 Cir. 1923, 286 F. 84. We think "harmless" is also to be so construed.

The Secretary would concede, apparently, the possibility that a person might consume Red 32 in such small quantities that no hazard to health would result. His guarded statement is that "the evidence so far available does not establish a likelihood of injury to man from the minute

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[26] Cf Palsgraf v. Long Island Railroad Co., 248 N.Y. 339, 162 N. E. 99, 59 A.L.R. 1253.

amount likely to find its way into the human diet from the consumption of such colored oranges at the level of use involved." [27] The Commissioner of Food and Drugs has admitted that there was no evidence of injury to consumers of colored oranges.[28] The Secretary has made no effort to ascertain whether or not there is, in fact, any likelihood of injury to the health of persons who consume oranges colored with Red 32. Taking the position that no quantitative test is authorized, the Secretary disclaims any power to fix a tolerance for the use of Red 32 in the coloring of oranges or for any other particular use. Under this theory it would make no difference whether or not there was a minimum quantity of Red 32 which would not be injurious. Malum in uno, malum in omnibus, is the departmental canon of construction.

[fol. 302] Unless the quantities of Red 32 used in the coloring of oranges are dangerous to public health, the objects and purposes of the Act will not be promoted by a construction which prohibits that use in such quantities. The statute which we construe provides for the fixing of tolerances for added poisonous and deleterious substances required in the production of food [29] and, by a 1954 amendment,[30] for the fixing of tolerances for poisonous pesticides on raw agricultural commodities. We cannot see how the objects and purposes of the statute would be furthered by a construction which permits safe, i. e. harmless, quantities of poisons other than coal-tar colors to be added to food where required in its production, and which permits safe tolerances of poisons for pesticides, but prohibits the use of a coal-tar color in the most minute and harmless quantity because it is harmful and injurious in large quantities. Such a construction would be an unwarranted discrimination, not so much against the coal-tar color and the manufacturers of it, but against that important segment of the orange producers who are economically dependent upon it. The construction of the Secretary results, or may result, in inequality and injustice. There is, we think, a more reasonable interpretation in the Act.

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[27] Hearing, supra, p. 3.

[28] Hearing, supra, p. 18.

[29] 21 U.S.C.A. § 346(a).

68 Stat. 511, 21 U.S.C.A. § 346 a.

The Secretary found that Red 32 is toxic; in other words that it is poisonous. The evidence justified the finding. If the Secretary is correct in his construction of "harmless", Section 402 (a) of the Act is inapplicable to coal-tar colors. If his construction is erroneous, Section 402 (a) would apply. If Section 402 (a) applies, the colored oranges would be "adulterated" only if the added poisonous [fol. 303] substance was unsafe within Section 406 (a). Under this section poisonous substances are permitted to be added to food if it "is required in the production thereof" within such limits as to quantity or extent as the Secretary finds necessary for the protection of public health. The Committees of the Senate and the House of Representatives each found that the practice of coloring oranges has become an economic necessity for a major segment of the orange industry since a high percentage of the oranges grown in Florida and Texas would meet with strong consumer resistance if not colored.[31] It is as important for a food to be marketable as for it to be palatable and, if the findings of the Committees be correct, then the addition of color is "required in production", as that phrase is used in the Act. Section 402 (a) and Section 402 (c) are not mutually exclusive. A coal-tar color may not be added unless from a certified batch. By Section 406 (b) only those coal-tar colors may be certified which the Secretary has listed as harmless. The Secretary and his colleagues in the Department did not oppose the enactment of the 1956 amendment to Section 40 (c). A reason given was that during the period of the moratorium a "non-toxic color" might be developed. It is the contention of the petitioners that no colors other than Red 32 and the others banned by the Secretary's order are effective. If another color be found which is not a coal-tar color but is as much or more toxic, then we see no reason to doubt that the Secretary would be required to deal with it under Section 406 (a) and to provide tolerances for its use in the event it could be used in any limited quantity without being injurious to the public health. The Secretary, in his order, has stated that "the Department [fol. 304] has no means of controlling the amounts of colors used in a variety of foods, drugs and cosmetics". It is not

[31] S. Rep. 2391, supra; H. R. Rep. No. 1982, supra.

apparent that this is a problem with respect to other toxic substances which are added to food under tolerances fixed by the Secretary and nothing is shown to indicate that it would be a problem in dealing with a coal-tar color. We see no reason for supposing that Congress intended to permit the use of toxic substances, including toxic colors other than coal-tar products, in safe and harmless quantities and to prohibit the use of toxic coal-tar colors in safe and harmless quantities. We do not ascribe such an intention to Congress. Another reason given by the Secretary for not opposing the 1956 amendment was that the moratorium for Red 32 would permit further exploration of its toxicity. It is the view of the Secretary that if it be found that the coloring of oranges with Red 32 is not injurious to humans and can be continued with safety, further legislation will be required. With this conclusion we do not agree.

We construe the Act as requiring the Secretary, under Section 406 (a), to determine whether the use of the color Red 32 is required in the production for market of oranges grown by a substantial segment of the orange producing industry; and if he finds that such use is so required, then to determine the quantity, if any, that can be tolerated as safe, and by regulation to limit the quantity to such extent as he finds necessary for the protection of public health. With "harmless", as used in Section 406 (b), construed as a relative rather than an absolute term, regulations promulgated by the Secretary under that section as well as under Section 406 (a) could be issued if the prerequisite [fol. 305] findings as to the necessity for using color had been made and the tolerance limits had been fixed.

In the order of the Secretary it is stated that there is no "authority to limit a color, once certified, to a single food—for example, F D & C Red No. 32 for use in color-added oranges". Although there may be no express statutory provision authorizing the limiting of the use of a color to a single food, it is not prohibited. If the adding of a toxic substance to one food may be harmful, but harmless when added to another food in limited quantities fixed by a predetermined tolerance, we are of the opinion that the Secretary is empowered to permit its use in the latter instance. The Secretary at one time seemed of the same opinion. In the Food and Drug Administration Regula-

tions promulgated in 1955, a number of coal-tar colors were listed for certification for use in food, drugs and cosmetics. Among these are colors designated as "lakes". The regulations provide that "No lake listed in paragraph (a) of this section shall be certified for any use in food except external application to shell eggs."[32] We shall not indulge in speculation upon the comparative porosity of egg shell and orange peel. We merely observe that the Secretary restricted the use of a group of coal-tar colors to a single food, and we think he was fully empowered to do so.

We are not unmindful of the admonition of the Second Circuit in the Certified Color Industry case, *supra*, that:

> "Now that their toxicity has been amply demonstrated it would be unconscionable for any court to require the Secretary to permit their use without the [fol. 306] clearest and most uncompromising evidence that usage at certain levels was absolutely safe." 236 F. 2d 870.

With this statement we are in accord. The findings of fact are to be made by the Secretary. Such findings, under Section 701 (f) (3) of the Act,[33] are conclusive if supported by substantial evidence.[34] We again advert to the Secretary's letter to the Chairman of the Committee of the House of Representatives at the time it was considering the 1956 amendment. The Secretary said:

> "While the scientific evidence so far available does not establish what the lowest safe dosage would be to test animals, neither does it establish a likelihood of injury to man from the use of this color [Red 32] on the exterior of oranges at the levels of use involved. Before final conclusions can be drawn on this point, however, it is necessary to conduct adequate scientific studies of chronic toxicity on laboratory animals over their life span, which will involve feeding tests at levels related to the quantities of such externally applied color that might enter man's diet. Such tests

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[32] 20 F.R. 9554, 21 C.F.R. § 9.3 (c).

[33] 52 Stat. 1055, 21 U.S.C.A. § 371 (f) (3).

[34] See Byrd v. United States, 5 Cir. 1946, 154 F.2d 62.

and studies will require approximately 3 years. We assume that the industry will make such studies."[35]

Since the Secretary is authorized by Section 702 (a) of the Act[36] to conduct examinations and has a technical staff already familiar with the problem, we think it not amiss, in view of our decision here, that we suggest consideration [fol. 307] be given by the Department to continuing or resuming the tests and studies from which the evidence was obtained which was adduced before the departmental hearing.

In the Certified Color Industry case, *supra*, the court rejected the Secretary's construction of the word "harmless". It holds that the government need not prove that a coal-tar color is in fact injurious to health but it is enough if it shows that it "might render the article of food injurious", adopting the quoted words from the Lexington Mill case. Because, in the quantities tested, the possibility of injury to health was indicated, the court sustained the order. It held that "under the circumstances disclosed in the record" the petitioning manufacturers of coal-tar colors could not require the Secretary to establish tolerances fixing safe levels of use. For this position two reasons were assigned, first that safe levels have not been established, and second, the department could not control uses within tolerance limits if such limits were prescribed. In connection with the first of these grounds the court comments that the industry made no investigation as to the effect of the colors at low levels of usage. The record bears out the court's observation, but under the Secretary's construction of the Act the effect of the colors at minimal levels would be immaterial. The inability to control the quantity used is no different, as we see it, in dealing with a coal-tar color than with respect to other toxic or poisonous substances where the Secretary is required to establish tolerances. In any event, as the court in the Certified Color Industry case points out, the situation before it was different from the case of a single color such as Red 32 [fol. 308] applied to a single use such as the coloring of oranges. Such a case is the one before us.

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[35] Hearing, supra, p. 3.

[36] 52 Stat. 1056, 21 U.S.C.A. § 372 (a).

After a hearing in 1939 Red 32 was found to be harmless and suitable for use in foods, drugs and cosmetics. The situation as presented on this review was briefly and accurately characterized in a letter from the Commissioner of Food and Drugs to Florida Senators and Congressmen written February 8, 1955. In speaking of Red 32 the Commissioner said:

> "Recent investigations show that these colors when fed in substantial amounts, show evidence of toxicity. There is, however, no evidence that, in the amounts used, and in the manner of use, in the coloring of citrus fruit, the product so colored is not safe for human consumption."

Unless there is evidence that, in the amounts used, and in the manner of use, oranges colored with Red 32 are unsafe for human consumption, the 1939 finding should not be supplanted by a contrary ruling by which such use is prohibited. It may be parenthetically observed that "unsafe" is the yardstick for determining tolerances under Section 406 (a). A determination may be made by the Secretary on his own initiative or upon the petition of any interested person[37] as to whether coloring is required and, if so, as to whether Red 32 is a harmless coal-tar color for use in coloring oranges and to fix the tolerances, if any, as may be proper for such use. [fol. 309] At the outset of this proceeding, upon agreement, a stay order was entered to permit the use of Red 32 in coloring oranges while the proceeding was pending. Except as to duration, the substance of the stay order's provisions is followed in our disposition of the matter.

The order promulgated by Marion B. Folsom, Secretary of Health, Education and Welfare, on November 10, 1955, published in the Federal Register on November 16, 1955, (20 F. R. 8492) will be set aside in so far as said order removes the coal-tar color FD&C Red No. 32 from the list of colors which may be certified for use in coloring the skin of oranges meeting minimum maturity standards prescribed in the State of Florida and Texas;

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[37] 52 Stat. 1055, 21 U.S.C.A. § 371(e).

provided, that nothing herein or in the judgment of this Court entered pursuant hereto shall restore said coal-tar color to the list of colors which may be certified for unrestricted use in food, drugs and cosmetics but shall operate to authorize the certification of batches of said color conforming to the specifications for the color appearing at 21 C. F. R. 135.3 (1949 ed.) for the purpose of coloring the skin of mature oranges only; provided further, that the Secretary shall be required to certify only suffiient batches of FD&C Red No. 32 as may be necessary to color the skin of mature oranges from time to time; provided further, that the certificates issued for batches of FD&C Red No. 32 may be limited by their certificate for use in coloring mature oranges only; and provided further, that nothing herein or in the judgment of this Court entered pursuant hereto shall be deemed to restrict the Secretary from making further investigations and conducting hearings for a determination of [fol. 310] whether the use of Red is required in the production of oranges and to determine the tolerances, if any, that are safe and harmless, as harmless is herein construed and defined.

Judgment accordingly will be entered setting aside in part, as herein set forth, the aforesaid order of the Secretary.

HUTCHESON, Chief Judge, Dissenting:

I am of the clear opinion that the result reached and the conclusions stated by the majority are unwarranted in law, and also, with respect to the findings of the Secretary of Agriculture, represent a case of judicial fiating which, though it has sometimes found favor in other courts (Cf. *Quaker Oats* v. *Security*, 129 F(2) 76, reversed 318 U.S. 218), has not until now found favor here. Cf. *Byrd* v. *U.S.*, 154 F(2) 62.

Because I am of this opinion, I feel constrained not only to note my dissent but to point out as briefly and as effectively as I can the patent errors on which the opinion proceeds. Because, too, it is clear to me that, while certainly presenting matters material for legisla-

tive consideration, it as certainly does not present matters material to the determination of the issue presented here, which is not what the law ought to be but what it is, I pass, with no more than comment, the basic assumption of the opinion, that the effect upon the future of the industry of our construction of the statute is the con- [fol. 311] trolling consideration in this case, to go at once to the controlling issues which are presented for decision here.

The first of these, as stated on page 12 of the majority opinion, is whether the questions presented for our review are the identical questions which were decided by the Second Circuit in the *Certified Color Industry Committee* v. *Secretary of Health, Education and Welfare* (2 Cir) 1956, 236 F(2) 866.

The second, as the majority opinion states it on page 15 is "whether the Secretary of Health, Education and Welfare is required or permitted to determine if there is a minimum quantity of the coal-tar color, designated as FD&C Red #32, which can be used in adding color to the skins of mature oranges without danger of impairing the health of those who consume such oranges, and, if so required or permitted and if it be determined that there is such a minimum, should the Secretary be required to list and certify such color for such uses".

The third and last, as stated on page 24 of the majority opinion, is whether "If it be found that the coloring of oranges with Red 32 is not injurious to humans and can be continued with safety, further legislation will be required".

I take up these questions in turn to say of the first that I not only find myself in complete agreement with the respondent's position that the decision in the Certified Color case is in point, is correct, and should be followed here, but I find completely unconvincing the arguments of the majority in support of its contrary view, that the [fol. 312] case is not in point. Indeed, it seems to me that the fact alone that the orange industry was not a party to the appeal in the Certified Color case is, from the standpoint of that case as a precedent, as completely

insubstantial as the classic difference claimed to exist between a white and a black horse case.

In short, the test of what was at issue and decided in, and what was the effect of, the decision in the Certified Color case, as compared to this one, is to be found in a resort to the opinion in that case. Such a resort will show that the precise question here argued, the meaning and effect of the statute, was determined not with particular reference to the nature and character of the business of particular appellants but upon the basis of a construction of the present statute as compared to former statutes, in the light of the decisions construing and applying them. With deference, the majority has completely misread and misapplied the statement in the opinion in the Certified Color case at p. 871, "*Thus the problem is far different from the one presented recently to Congress when the act was amended to permit the use of Red 32 on orange skins not intended for processing*". (emphasis supplied)

In making this statement, the court was not, as the majority in this case seems to think it was, stating that, as applied to oranges, *the construction of the statute under review and the duty of the secretary under it* would be different from the construction of the statute and the duty of the secretary as applied to products generally. In making the statement the court was stating correctly that, viewed from the standpoint of legislative relief by [fol. 313] amendment, the problem presented was different from the one presented to the secretary in proceeding under, and the courts in construing, the statute before it was amended. The court was not at all suggesting that the existing statute gave the secretary any different discretion or authority in respect to oranges than in respect to other products. To have so held would have been in effect to hold that the statute under review here gave the secretary authority in his discretion to consider and determine, product by product, whether he could and should establish tolerances, and this in the face of a statute containing no such language and differently construed both by the Executive or the Legislative branch.

In its treatment of the second question, the majority, acting under the influence of the same idea which dictated

its rejection of the result and the reasoning in the Certified Color case, that the situation and needs of the Texas and Florida orange industry make a special case out of their complaint and requires a construction of the statute based not upon the language used but upon general legislative considerations as to what such an act ought to provide, draws for the support of its view upon the Lexington Mill case, *U.S.* v. *Lexington Mill & Elev. Co.*, 232 U.S. 399, decided under an entirely different statute, that of 1906, and containing entirely different provisions from those under construction here. It seems clear to me that no sound reason is presented, and no support is found in either the language, the legislative history of the statute under construction, or the authorities cited, for the view of the majority that the Secretary's finding, quoted fully with approval in the Certified Color case at p. 871, was wrong and must be set aside.

[fol. 314] Finally, while the answer of the majority, to the third and final question, whether the needs of the industry can be taken care of without additional legislation, that it can be, follows naturally enough from what has gone before, it seems clear to me that it is nothing more than a complete tour de force, the substitution of judicial for congressional legislation. Though the Executive and Legislative branches of the government have determined that the 1956 amendment to Sec. 402(b) was necessary in order to give the secretary the power to determine tolerances as to coal tar products, the court, differing with both, has held that it can and should by its order in effect say, we will construe the statute, and by order give effect to our construction, so as to make unnecessary, indeed useless, the 1956 amendment or any future congressional legislation, and with the Secretary thus panoplied in the judicial fiat as to his authority under the statute before its amendment, and compelled by the judicial order to give that fiat effect, Congress, the Secretary and the Texas and Florida Industries need trouble themselves no more, but, resting securely upon the judicial legislation and order, they may all go about their business in the future untroubled and undisturbed.

It is one thing for a court to construe a statute. It is quite another for it to rewrite it. I respectfully Dissent

from what I regard here not as a construction but a rewriting of the statute.

[fol. 315] IN UNITED STATES COURT OF APPEALS

No. 15934

FLORIDA CITRUS EXCHANGE, et al.,

vs.

M. B. FOLSOM, Secretary of the Department of Health, Education and Welfare.

JUDGMENT—July 12, 1957

This cause came on to be heard on the petition of Florida Citrus Exchange, and others, for review of an order of the Secretary of Health, Education and Welfare issued on November 10, 1955, and was argued by counsel;

On consideration whereof, It is now here ordered, adjudged and decreed by this Court that the order of the Secretary in this cause be, and the same is hereby, set aside in part, in accordance with the opinion of this Court.

"Hutcheson, Chief Judge, dissenting."

[fol. 316] IN UNITED STATES COURT OF APPEALS

No. 15948

FRANK R. SCHELL,

vs.

M. B. FOLSOM, Secretary of the Department of Health, Education and Welfare.

JUDGMENT—July 12, 1957

This cause came on to be heard on the petition of Frank R. Schell, for a review of an order of the Secretary of Health, Education and Welfare issued on November 10, 1955, and was argued by counsel;

On consideration whereof, It is now here ordered, adjudged and decreed by this Court that the order of the Secretary in this cause be, and the same is hereby, set aside in part, in accordance with the opinion of this Court.

"Hutcheson, Chief Judge, dissenting."

[fols. 317-330] Petition for rehearing covering 14 pages filed July 31, 1957. Omitted from this print. It was denied, and nothing more by order. August 28, 1957.

[fol. 331] [File Endorsement Omitted]

IN THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

No. 15934

FLORIDA CITRUS EXCHANGE, et al., Appellants,

vs.

M. B. FOLSOM, Secretary of the Department of Health, Education and Welfare, Appellee

No. 15948

FRANK R. SCHELL, Appellant,

vs.

M. B. FOLSOM, Secretary of the Department of Health, Education and Welfare, Appellee.

On Petitions for Review of an Order of the Secretary of Health, Education and Welfare.

ORDER DENYING PETITION FOR REHEARING—August 28, 1957

Before HUTCHESON, Chief Judge, and Jones and Brown, Circuit Judges

Per Curiam

It is ordered that the petition for rehearing in the above entitled and numbered causes be, and it is, hereby denied.

HUTCHESON, Chief Judge, Dissenting.

[fol. 332-335] Clerk's Certificate to foregoing transcript omitted in printing.

[fol. 336]

Joint Appendix to Petitioners' Briefs and to Respondent's Brief

In The United States Court of Appeals, Fifth Circuit

No. 15934.

Florida Citrus Exchange, et al.,

versus

M. B. Folsom, Secretary of the Department of Health, Education and Welfare.

No. 15948.

Frank R. Schell,

versus

M. B. Folsom, Secretary of the Department of Health, Education and Welfare.

On Petition for Review of an Order of the Secretary of Health, Education and Welfare.

Explanatory Note.

By stipulation this is a joint Appendix for the Petitioners in the cases of Florida Citrus Exchange, et al., [fol. 337] vs. M. B. Folsom, Secretary of the Department of Health, Education, and Welfare, No. 15934, and Frank R. Schell vs. M. B. Folsom, Secretary of Health, Education, and Welfare, No. 15948, and on behalf of M. B. Folsom, Secretary of the Department of Health, Education, and Welfare, Respondent in both the foregoing cases.

The figures appearing in brackets to the left of the various pages are references to the pages at which the matter appears in the original record.

[195] Before the Secretary, Department of Health, Education, and Welfare.

In the Matter of: Amending Sections 135.3 and 135.11 of the Color Certification Regulations.

Docket No. FDC-60.

Room G-751, Health, Education & Welfare Building, Washington, D. C., Tuesday, January 19, 1954.

The above-entited matter came on for hearing, pursuant to notice, at 10:00 o'clock a.m.

Before Leonard D. Hardy, Presiding Officer.

* * * * * * *

[fol. 338] [200] TRANSCRIPT OF HEARING

Presiding Officer Hardy: Let's call the meeting to order.

On behalf of the Secretary of Health, Education and Welfare, I would like to welcome you ladies and gentlemen here today. My name is Leonard Hardy. I have been designated by the Secretary to hold this hearing in her stead.

The notice of hearing has been published. It was published in the Federal Register for December 19, 1953. I have five copies here which I will have marked in evidence as Exhibit No. 1.

(The document referred to was marked Exhibit No. 1 for identification and received in evidence.)

Presiding Officer Hardy: There are other copies available and I will pass them around. I don't believe there are enough for each person, so if you will share your copy with your neighbor it will facilitate matters.

The purpose of this hearing, as reflected by the notice, is to receive evidence to determine whether to amend the regulations for the certification of certain coal-tar colors. The particular colors designated in the notice and concern-

ing which we will receive evidence are known as FD&C Red No. 32, FD&C Orange No. 1 and FD&C Orange No. 2. [fol. 339] The present regulations are found in Title 21 of the Code of Federal Regulations, Sections 135.1 to 135.15. These [201] regulations include the coal-tar colors which I have just mentioned. The regulations were promulgated originally under the authority of Section 406 (b), 504, 604 and 701 of the Federal Food, Drug and Cosmetic Act.

Those are the same sections which are the basis for the authority for holding the present hearing. Section 406 (b) provides that the Secretary shall promulgate regulations providing for the listing of coal-tar colors which are harmless and suitable for use in food and for the certification of batches of such colors with or without harmless diluents.

Section 504 contains much of the same wording, in fact exactly the same wording, except it provides for the use of these colors in drugs.

Section 604 has exactly the same wording, except that it provides for the listing of colors which are harmless and suitable for use in cosmetics.

So apparently all three fields will be considered. Section 701 is the general authority for promulgating regulations and sets out the manner in which the hearings are to be held.

These hearings are also controlled by the, what is known as the rules of practice for hearing, which are set out in Code of Federal Regulations Section 1.701 through 1.715. Of course, the Administrative Procedure Act is the controlling authority as an Act of Congress, and it is the controlling authority in handling these hearings.
[fol. 340] [202] Now, I have here appearance forms which should be executed in full by all persons intending to participate in the hearing, or who may participate in the hearings. I want to pass these appearance forms around and we will take a few minutes to have these executed and passed back up front so that the record can show the appearance of all persons interested.

(Discussion off the record.)

Presiding Officer Hardy: The Rule of Practice provide for accepting affidavits on or before the date of hearing which are relevant and material to the issues before the hearing, and I would like to know if there are any affidavits that anybody desires to file at this time.

I have received one letter dated January 15, 1954, from McNeil's Laboratories, Inc., which they wish to file in lieu of their appearance at the hearing. The letter is not under oath, and therefore in that respect doesn't constitute an affidavit. The reading of the letter reveals it does not set forth any factual evidence, but merely draws conclusions from data submitted to the McNeil Laboratories by the Food and Drug Administration.

There is nothing in the letter to indicate that the writer, one Robert L. McNeil, Jr., is qualified to make deductions from the data submitted, and therefore I have to rule that this letter is not admissible as part of the record.

[fol. 341] This hearing is held on the initiative of the Secretary [203] of Health, Education and Welfare. Rules of Practice provide that the witnesses or the proponent of proposed amendments shall be heard first. Therefore, the Department's witnesses will go on the stand first.

Mr. Steffy, you are representing the Department?

Mr. Steffy: I am.

Presiding Officer Hardy: Are you ready for your first witness?

Mr. Steffy: I would like to call Dr. Vos to the stand.

Presiding Officer Hardy: Off the record.

(Discussion off the record.)

Presiding Officer Hardy: On the record.

Whereupon, BERT J. VOS, was called as a witness, and having been first duly sworn, was examined and testified as follows:

Direct examination.

By Mr. Steffy:

Q. Will you please state your name?

A. My name is Bert J. Vos.

[fol. 342] Q. What is your address?

A. I live on El Nido Road, just outside of McLean, Virginia.

Q. What is your present position?

[204] A. I am Assistant Chief of the Division of Pharmacology of the Food and Drug Administration, Department of Health, Education and Welfare.

Q. Will you state briefly your educational background and your experience?

A. I have a Bachelor's Degree in Chemistry from the Indiana University, in 1930; a Doctor of Philosophy in Physiological Chemistry from the University of Chicago, in 1934. A Doctor of Medicine Degree from the University of Chicago in 1937.

I interned for one year at the Billings Hospital of the University of Chicago in 1938.

I was an instructor in Pharmacology at the University of Chicago for approximately nine months, and in 1939, in October, I came to the Food and Drug Administration as associate pharmacologist and have been working for the Food and Drug Administration as pharmacologist since then.

* * * * * * *

Q. Are you a member of any professional societies, Doctor?

A. Yes, I am a member of the American Society for Pharmacology and Experimental Therapeutics, the Society for [205] Experimental Biology and Medicine, the American Association for the Advancement of Science.

Q. Have you published any scientific publications?

A. I have published approximately a dozen papers on various phases of pharmacology.

[fol. 343] Q. You stated you are Assistant Chief of the Division of Pharmacology of the Food and Drug Administration, is that correct?

A. That is correct.

Q. Would you state briefly your duties in that position?

A. In that position I assist the Chief of the Division of Pharmacology and participate with him in the supervision of the activities of the Division, which includes selecting projects for study, a broad supervision of the set-up of the experiments, and evaluating the results obtained therefrom.

Q. Does the Division of Pharmacology in the regular course of its business keep records of experimental work done in its laboratories?

A. Yes.

Q. Do you have access to these records, Doctor?

A. Yes.

Q. Has experimental work on certified coal-tar colors been carried on in the division of Pharmacology?

A. Yes. We have done considerable work in that field.

• • • • • • •

[206] Q. What was the source of the colors which you used in your experiments on FD&C Orange No. 1?

A. They were obtained from the Division of Cosmetics and from the color certification laboratory which preceded the present Division of Cosmetics.

Q. Is that the Division of Cosmetics and the Color Certification Laboratory of the Food and Drug Administration?

A. Yes, that is correct.

[fol. 344] Q. Who is in charge of that Division at the present time?

A. Dr. Clark. G. Robert Clark.

Q. Has the Division of Pharmacology also carried out experimental work on FD&C Orange No. 2?

A. That is correct.

Q. What was the source of the colors used in this experimental work?

A. It was the same source.

Q. Has the Division of Pharmacology also carried out experimental work on FD&C Red 32?

A. That is correct.

Q. What was the source of the color used in these [207] experiments?

A. All of that color was obtained from the same source as the preceding two, with the exception of two ingredients known as para-isomer and meta-isomer. These were obtained directly from a commercial firm.

Q. Is that a commercial firm ordinarily engaged in preparing FD&C Red 32 for use in foods, drugs and cosmetics?

A. I don't know.

Q. Will you explain the procedure followed by the Division of Pharmacology in conducting toxicity tests on animals?

A. The material to be tested is first selected and then there is a discussion as to the type of animals which should be used in the experiment, the approximate dosage levels on which the experiment should be started, and the experiment is then begun. The work is under the direct supervision of various pharmacologist. The actual administration of the drug to the animals or the mixing of it in test diets is done by technically trained individuals under the supervision of the pharmacolog-st.

[fol. 345] The animals are examined daily—perhaps I should say inspected daily. Any unusual appearance of the animals is immediately called to the attention of the pharmacologist in charge, and as the experiment progresses the results are discussed with the various members of the Division, including myself.

[208] Q. Was this customary procedure followed in conducting experiments with FD&C Orange 1?

A. Yes.

Q. Is that also true of the experiments conducted with FD&C Orange 2, and FD&C Red 32?

A. That is correct.

. . . . . .

[215] By Mr. Steffy:

Q. In addition to the tests which you have described which were performed on animals, Doctor, have you had any personal experience with FD&C Orange No. 1?

A. Yes. Several years ago a sample of candy was collected by an inspector of the Food & Drug Administration as a result of a complaint that the candy had caused diarrhea in a child. This sample of candy was tested by us in the Division of Pharmacology. When we administered it to rats we observed no [216] adverse effects. When it was tested on human volunteers, of which I was one, there was produced a marked abdominal griping and diarrhea. In my own case the results were obtained with 6 or 8 pieces of the candy. In some of the other volunteers who ate the candy, 4 pieces caused the diarrhea in one

person, and diarrhea was produced by 1 piece of candy in one person.

[fol. 346] As a result of testing the various ingredients of the candy we gradually narrowed the cause of the diarrhea down to the coal-tar colors which were used to color the candy, and finally to the individual color, FD&C Orange No. 1. When this color was tested on several individuals, doses of 100 or 80 milligrams, as a single dose, produced the marked griping and diarrhea which the candy itself had produced.

* * * * * * *

[217] Q. In connection with your duties at the Division of Pharmacology, have you also had occasion to conduct tests on FD&C Orange No. 2?

A. I have.

Q. Do you have with you the reports of the tests conducted on FD&C Orange No. 2?

A. I do.

Q. Would you hand me a copy of that report. Doctor, the report you handed me is entitled, "Chronic Toxicity of FD&C Orange No. 2 in Rats". At least that is the title of the first page. The report consists of 18 pages. In this document a report on all of the toxicity tests on animals conducted on FD&C Orange No. 2, since that color was admitted to listing?

A. Yes, it is.

Mr. Steffy: I ask this report be marked as Exhibit 3 for identification.

Presiding Officer Hardy: It may be so marked.

(The document above-referred to was marked Exhibit No. 3 for identification.)

[fol. 347] [218] Presiding Officer Hardy: Off the record.

(Discussion off the record)

Presiding Officer Hardy: On the record.

By Mr. Steffy:

Q. Doctor, will you briefly outline the nature of the experiments which are reported in Exhibit 3 for identification?

A. The first experiment was begun in 1939 and consisted of a two-year feeding test in rats, in which 24 rats were

placed on a diet containing 500 parts per million of FD&C Orange No. 2 mixed in a diet called Diet "A", which is described in the exhibit. A second group of 24 rats received the same diet without the added color in a parallel 2-year experiment. Groups of 18 rats were fed 500 parts per million and 100 parts per million of FD&C Orange No. 2 mixed in a low-protein diet, and a third group of 18 rats received the low-protein diet alone.

The original growth and mortality data on these two experiments is no longer available. The mortality data has been taken from the files of the pathologist and shows no effect on mortality as a result of feeding FD&C Orange No. 2 at these two levels.

However, in the examination of the animals by the pathologist, it was noted that there were changes in the hearts of the animals which had received 500 parts per million of FD&C Orange No. 2 in their diet, both in the animals on Diet "A" and in the animals in the low-protein diet. There was a [219] suggestion of certain other changes at the 100PPM—parts per million level, but occurred in only two animals.

[fol. 348] The next experiment on FD&C Orange No. 2 was begun in 1940. In this experiment 10 rats were fed a diet containing FD&C Orange No. 2. The concentration was 0.1 percent for the first 8 weeks of the experiment. After this the concentration was increased to 0.2 percent for the remainder of the experiment.

Table 1, on page 5, shows a marked depression of the growth of the animals as compared to the controls. There was no mortality during the first 8 weeks, but after the concentration was increased to 2/10 of a percent, deaths began to occur. 7 of the rats were found dead between the 9th and 22nd week of the experiment, and 3 were sacrificed in poor condition between the 13th and 17th weeks.

The median survival time is shown in Table 1. The control rats, half of them survived for 101 weeks whereas the median survival time for the animals on FD&C Orange No. 2 was only 15½ weeks. Pathological examination of the animals showed principally abnormalities in the livers. The changes are described as either focal coagulation necrosis, or a more diffuse subacute type of degeneration, or both.

Q. Will you state for the record, Doctor, where those changes are recorded in Exhibit 3 for identification?

A. The description is on the bottom of page 3 and the top of page 4.

[220] The next experiment is described on page 6 of the exhibit. In this experiment FD&C Orange No. 2 was incorporated in the diet of rats. Five rats were given a diet containing 0.1 percent of the color, and 10 rats were given a diet containing 0.25 percent of the color. Additional 5 animals served as controls and received a diet without added color. The results of the experiment are shown in Table 1, on page 6. There was a severe retardation of [fol. 349] growth at the .25 percent level, a marked retardation at 0.2 percent.

At the higher level there was an increased mortality of the animals, and the experiment was discontinued at the end of the 42nd day because of the mortality on the higher level. No pathological examination was made of these animals because they had been on the diet for such a short time.

The next experiment is described on page 7 of the exhibit. It was begun in 1953 and consisted of the subcutaneous injection of 18 rats with 0.1 milliliters of a 5 percent suspension of FD&C Orange No. 2 in glycerine. The injections were made subcutaneously once a week. Control animals were injected with glycerine alone. The object of this experiment was to determine if the color, when injected in this manner to rats, led to the production of tumors at the site of the injection. One of the rats which received the color died following 7 injections. A second died after 8 injections. And the injections were discontinued. A third rat was found dead 11 [221] days after the final injection of FD&C Orange No. 2. There were no deaths among the control animals. The experiment was discontinued after 8 injections because of the toxic effects.

The next experiment is described on page 8. It was begun in 1940 and involved subcutaneous injection of FD&C Orange No. 2 into two groups of 18 mice. The amount of color injected each time was 12.1 milligrams. The injections were made with a modified trocar into the right axillary region, subcontaneously.

The injections were made at irregular intervals, 8, 19, 24, 30, and in one case, 55 weeks after the initial injection.

There were no tumors seen at autopsy by gross examination of the animals.

[fol. 350] The next experiment, which is described on page 9 of the exhibit, was begun in 1938 and involved the administration of FD&C Orange No. 2 to dogs. The first dog received 100 milligrams per kilogram per day in gelatin capsules for a period of about 11 months. Following this the dose was reduced to 20 milligrams per kilogram per day and was continued for 60 months. The second dog was started on 100 milligrams per kilogram per day given as an oil solution by stomach tube for about a month. The dose was then reduced to 20 milligrams per kilogram per day for about a month, and finally to 5 milligrams per kilogram per day administered in capsules. This dose was continued for 62 months.

[222] In the case of the first dog the dose was reduced from 100 milligrams because the dog was in poor condition as a result of this dose. When the dose was reduced to 20 milligrams per kilogram per day the color was tolerated and the dog gained weight. It was sacrificed in good condition after 60 months on this dose. The dose in the second dog was reduced, first from 100 milligrams per kilogram per day to 20 milligrams per kilogram per day, and finally to 5 milligrams per kilogram per day because the dog was not eating well, and was gaining weight slowly on the higher doses. The 5 milligrams per kilogram per day was tolerated and the dog was sacrificed apparently in good condition after 62 months on this dose.

In this period of time the dog had 6 litters of puppies, which were of average size and health.

Examination of the dogs after sacrifice, revealed only the moderate atrophy of testis and prostate of the male dog, and since this is an isolated observation, no significance is attached to it.

[fol. 351] The next experiment started as described on page 11. This experiment was begun in 1953 and involved the administration of FD&C Orange No. 2 to dogs. Four dogs were started on a diet containing 0.2 percent of the color. They showed diarrhea for the first few days on this diet. They ate poorly, lost weight steadily. On the 28th day of the experiment two of the dogs were sacrificed in ex-

tremis. They had lost respectively 43 and [223] 32 percent of their initial weight. The remaining two dogs had lost 31 and 21 percent of their initial weight, respectively. They were placed on a normal diet for 9 days, and during this rest period, they regained some weight and improved their physical condition. Then with two additional dogs they were placed on a diet containing 0.04 percent FD&C Orange No. 2. On this diet the four dogs did well for about a month. Following this they began to eat poorly and lose weight. On the 75th day of this concentration the first of the four dogs was found dead. The second was found dead on the 95th day. The third was killed in extremis on the 98th day. The 4th was found just at death, on the 124th day. All four dogs had lost approximately 50 percent of their body weight prior to death.

Pathological examination of the animals showed emaciation. One dog had a moderate amount of fluid in the peritoneal and pleural cavities. On microscopic examination the basic pattern was atrophy and/or cellular depletion of the various organs; the most frequently being affected was the liver, spleen, bone marrow, genital organs, skeletal muscle, and lymph nodes.

In the final experiment on this color, which is described on page 18 of the exhibit, was conducted in 1952. In this experiment 5 of the 11 dogs which had been found sensitive [fol. 352] to the cathartic action of FD&C Orange No. 1 were tested with FD&C Orange No. 2. The drug was administered at a [224] dose of 200 milligrams per dog in capsular form. All 5 of the dogs developed diarrhea within 8 hours after the administration of the capules.

Q. Does Exhibit 3 for identification contain a complete summary of these tests which you have described, including the pathological results?

A. Yes, it does.

Q. Are the original data sheets available for inspection for any interested parties?

A. With the exception of the first experiment described on page 1, for which the original data sheets have been destroyed—the original data sheets of the remainder experiments in the exhibit are available.

OFFER IN EVIDENCE

Mr. Steffy: I ask Exhibit 3 for identification be received in evidence.

Presiding Officer Hardy: Is there any objection? Let it be so received.

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[225] Mr. Steffy: Has Exhibit 3 been received in evidence?

Presiding Officer Hardy: Is there any objection to the admissibility of Exhibit 3 in evidence? It may be so received.

By Mr. Steffy:

Q. On the basis of the tests reported in Exhibit 3, and on the basis of your education, training, and experience, [fol. 353] do you have an opinion as to whether FD&C Orange No. 2 is a harmless coal-tar color?

A. I do.

Q. What is that opinion?

A. It is my opinion that it is not a harmless coal-tar color.

Q. In connection with your position in the Division of Pharmacology, have you had occasion to conduct experiments with the coal-tar color known as FD&C Red No. 32?

A. We have.

Q. Do you have with you reports of those experiments?

A. I do.

Q. Is the report to which you refer a 29-page report, the first page of which bears the title, "Chronic Toxicity of FD&C Red No. 32 in Rats"?

A. It does.

Mr. Steffy: I ask that this report be marked as Exhibit No. 4 for identification.

• • • • • • •

[226] By Mr. Steffy:

Q. Doctor, will you outline briefly the nature of the experiments which are reported on in Exhibit 4 for identification?

A. The first experiment was begun in 1940 and is reported on page 1. It shows that a 0.1 percent concentration

of FD&C Red 32 in the diet of rats markedly depressed the growth and reduced the median survival time.

[fol. 354] The second experiment is reported on page 2. It was begun in 1941. It shows that 0.1 percent of FD&C Red No. 32 retarded the growth of rats and reduced the median survival time.

The pathological examination of the rats in the two preceding experiments is described on page 3. It shows an effect on the liver of the rats treated with the color. The principal changes are bile duct proliferation, hyperplasia of the hepatci cells, irregularly mixed with areas of atrophy, and moderate or marked central lobular hepatic cell necrosis.

The next experiment was begun in 1951 described on page 4. In this experiment FD&C Red No. 32 was added to the [227] diet of rats at various concentrations. At a 2 percent level all rats were dead within 7 days. At a 1 percent level all died within 12 days. When weanling rats were given 0.5 percent they died within 21 days. Slightly older rats given 0.5 percent, 3 of the 5 were dead in 26 days, the remaining two were sacrificed when their weight decreased. At 0.25 percent two rats died in 7 and 6 weeks, the remaining 3 were sacrificed at the end of 10 weeks.

. . . . . .

[228] This experiment was begun in 1952 and involves the feeding of FD&C Red No. 32 in the diet of the rats. The results show that there is a marked effect on mortality at a level of .25 per cent, a less pronounced effect on mortality at 0.1 per cent, a marked retardation of the growth in both groups.

Moderate to severe anemia, depending on the dose, and an increase in the white cell count.

. . . . . .

[fol. 355] Pathological examination of the rats in this experiment is described on pages 8 to 17 of the exhibit. The outstanding features were moderate to marked liver damage at the 0.25 per cent level of the diet, slight to moderate liver damage and heart lesions at the 0.1 per cent level of the diet.

. . . . . .

[229] The next experiment is described, beginning on page 18 of the exhibit. It was begun in 1953, and involved the testing of FD&C Red No. 32 for carcinogenicity injection into rats. In the first experiment the weekly dose was gradually increased to approximately ten milligrams per rat and resulted in such toxicity that the experiment was discontinued.

The table 1 shows the blood count of the animals which received the color, and it shows marked anemia as the experiment progresses. The counts shown for the ninth week were taken 12 days after the last injection and show a beginning improvement in the count.

In the second experiment, which was set up for the same purpose, it was set up in conjunction with a similar test of FD&C Orange No. 2, and when that latter color showed evidence of toxicity the entire experiment was discontinued since the experiment had been set up with litter-mate animals. When the one part was stopped the entire experiment was stopped.

In neither of those two tests was the experiment conducted [230] long enough to reach any conclusion as to the possibility of carcinogenicity by repeated subcutaneous injection of rats.

[fol. 356] The next experiment is described on page 20, and consists of the subcutaneous injection of FD&C Red No. 32 into mice at irregular intervals. There was in this experiment no evidence of carcinogenicity found.

The next experiment is described beginning on page 21. It was begun in 1938 and involved the administration of FD&C Red No. 32 to dogs. Five dogs received a dose of five milligrams per kilogram per day for a period of five to six years, and were sacrificed at the end of this period in apparently good condition.

One of these dogs had received a dose of one hundred milligrams per kilogram per day for approximately a month, which was later reduced to 20 milligrams per kilogram per day for approximately a month. An additional dog received one hundred milligrams per kilogram per day for about ten months and was later put on 20 milligrams per kilogram per day which was continued for approximately five years.

In addition, one of the constituents of FD&C Red No. 32, the para-isomer was administered to two dogs at a

dose of five milligrams per kilogram per day for six years and the meta-isomer was administered to three dogs at a dose of five milligrams per kilogram per day also for six years.

The two dogs which received one hundred milligrams per [231] kilogram per day of FD&C Red No. 32 showed moderate weight loss, while this dose was being given.

Pathological examination of the animals following sacrifice showed no changes which would be attributed to treatment.

The next experiment is described starting on page 23. It was begun in 1953 and involved the administration of FD&C Red No. 32 by incorporating it in the diet of dogs. Four dogs were started on a level of 0.2 per cent of [fol. 357] the color. Two of these were sacrificed at the end of 26 days after they had lost 28 and 29 percent of their weight. The other two dogs were placed on a control diet for ten days, and then after they had regained weight and improved their condition they were placed with two additional dogs on a diet containing 0.01 per cent of FD&C Red No. 32.

One of those four dogs lost approximately 60 per cent of its body weight and was found dead after 173 days on the diet. The remaining three dogs have lost some weight, but appear in fair condition after approximately ten months on this diet. The four dogs were fed 0.04 per cent of FD&C Red No. 32 in their diet. They lost weight up to about 50 per cent and were sacrificed in extremis at 124, 137, 148 and 148 days on the experiment. There was sporadic diarrhea observed during the experiment.

The pathological examination of these dogs is described on pages 24 to 28 of the exhibit. The findings were slight or [232] moderate pallor of the organs and tissues in general, gelatinous bone marrow, and atrophy of the liver as judged by gross examination.

The microscopic examination, the principal feature was atrophy and/or cellular depression of the various organs, such as the liver, spleen, lymph nodes, bone marrow, genital organs, and skeletal muscle.

The final experiment in FD&C Red No. 32 is described on page 29. It was conducted in 1952. Ten dogs which had previously been found sensitive to the carthartic action

of FD&C Orange No. 1 were tested on FD&C Red No. 32. When they were given two hundred milligrams of FD&C Red No. 32 per dog, eight of the ten developed diarrhea. Five dogs were later tested with a dose of one hundred [fol. 358] milligrams per dog, and four developed diarrhea and one gave questionable results.

* * * * * * *

[233] Q. On the basis of the experiments which you have described, and which are reported in Exhibit 4, and on the basis of your education, training, and experience, do you have an opinion as to whether FD&C Red No. 32 is a harmless coal-tar color?

A. I do.

Q. What is that opinion?

A. My opinion is that it is not a harmless coal-tar color.

* * * * * * *

[235] Q. Dr. Vos, I noticed in Exhibit 2, 3, and 4 you specify the levels of feeding in different terms, sometimes in percentage, sometimes in milligrams per kilo, and other times in parts per million.

I wondered if we could convert some of those things into something we are familiar with. In percentage, that would be simple enough, that is just arithmetic, isn't it?

A. Yes.

Q. In those parts of your exhibits where you talked about milligrams per kilo, I was not able to find the amount of the diet, and is there any basis to at least approximate those levels in values of parts per million?

A. It could be done accurately only by referring to the actual amount of diet which the animals ate and then computing it in those terms. Of course, the material was given in a single dose, it was not diluted through [fol. 359] the diet, so the two experiments are not strictly comparable, as they are both toxicity experiments, but in one case the material was given in a single dose and in the other experiment it was diluted in the diet.

Q. I see.

[236] A. As a rough approximation, in the case of rats, if you will—in the case of young rats—if you will multiply the milligrams per kilogram per day by ap-

proximately ten, you will get a figure which corresponds to parts per million in the diet.

Q. Could you make a like assumption in the case of dogs for estimate purposes?

A. The discussion which I just had before applies as to the difficulty of relating the two experiments, but for a rough approximation, if you multiply the milligrams per kilogram per day, in the case of dogs, by a figure of approximately 40, you will—

Q. That will give you parts per million roughly.

A. That will give you roughly parts per million per diet. That is based on the average consumption of food by dogs.

. . . . . .

Q. Well, while we are on that page, I notice those percentages there, while it is only arithmetic, but for convenience [237] may we go down the line.

2.0 per cent would mean 20,000 parts per million, is that correct?

A. Yes.

Q. That is the third line?

A. Yes.

Q. And 0.5 per cent would be 10,000 parts?

A. Five thousand.

[fol. 360] Q. No, one per cent would be 10,000 parts, and 0.5 per cent would be 5,000, and so on, down the line. Can you tell us the rationale on the basis on which you select these levels, and the other levels in the experiment that you had?

A. No. These were simply levels that were selected after a consideration of some extent of work which had been done previously, and an attempt was made here to cover quite a wide range of dosages which would give a clue to a proper dose or set of doses to select in a subsequent experiment.

. . . . . .

A. In general, in a toxilogical study we attempt to administer the compound under investigation at a series of levels, [238] some of which will produce no effect, some a slight effect, and others a marked effect. Obviously, in

some of these experiments where the color was given at only one dosage level in the experiment it would be impossible to achieve all of those ends.

• • • • • • •

Q. Well, then, these levels were not specifically related to the levels of these colors as actual-y used under normal conditions of use?

A. No, that was not a part of this.

Q. Have you any evidence at such levels where the capacity for producing harmful effects was tested at levels of ordinary normal conditions of use?

A. I have very little information on the matter of what the customary levels of use are.

[fol. 361] Q. Well, as I understood it, you didn't need that for your purposes?

A. That is right.

Q. Because your tests were not related to that at all. About that candy incident: Do you know what the level of the [239] dye was in that candy?

A. I understand that it was seven-hundredths of a per cent.

Q. Seven-hundredths of a per cent. That would be approximately a million?

A. Seven hundred parts of a million.

• • • • • • •

By Mr. Markel:

Q. Dr. Vos, then, you have no evidence as to the capability of producing harmful effects of any of these colors at the level of ordinary use under normal conditions of use, I should say?

[240] A. Without having a more thorough information on the actual level of ordinary use I would hesitate to answer that question.

Q. Well, you have no evidence at levels other than the levels appearing in the exhibits?

A. That appear in the exhibit, that is correct.

Q. Aside from the experiments that you have referred to here, do you know of any other evidence of injury to humans except this child that ate this candy as you have described?

A. It is my impression there was a second report of injury with this same candy. I have been unable to locate that report so that as I say that is my impression that there was a second instance reported while we were investigation the first sample.

[fol. 362] Q. But except for this specific candy instance, you have no information?

A. That is correct.

* * * * * * *

[241] By Mr. Holloway:

Q. Dr. Vos, have you conducted any tests or experiments other than by feeding or by direct injection into an animal to determine the effect of the subject colors?

A. No, I have not. Perhaps I might amplify that. We are in the process of settting up experiments in which we will study [242] the effect of these colors applied topically. The experiment is just in the process of beginning, and we have no results at all to date.

Q. You have no tests or form no conclusion of the use of subject colors for use on the skin or in any cosmetics?

A. That is correct.

Q. Including lips?

A. That is correct.

Q. When you, in response to a question, which was based on your experiments and the tests and your own experience, the question being whether or not in your opinion you considered each of the three subject colors harmless, and you stated that in your opinion they were not harmless.

Were you using the term "harmless" then in the absolute sense that each of the colors were capable of producing harm?

A. That is correct.

Q. In that sense, then, is not common salt capable of producing harm?

[fol. 363] A. Well, I believe in the case of common salt you have to take into consideration the fact that it is essential to live, so that since you can't get along without some salt, I don't think you could ordinarily consider salt harmful.

Q. Nevertheless, if you took salt in a quantity of two or three ounces, you may get some bad results from salt?

A. There would be some adverse effects from two or three [243] ounces of salt, yes.

Q. Then all your experiments and tests tended to show some resulting harm depending on the quantity fed?

A. That is correct, or injected.

Q. Or injected?

A. Yes.

Q. That is, when it was fed in certain percentages or certain dosages or in certain percentages of the diet?

A. That is correct.

Q. Or in relationship of the weight of the animal fed?

A. Yes.

Q. Are the bases of your experiments, and the test experiments, been, that you have no basis of an opinion as to harmfulness when any of the subject colors are used for other than feeding or injection?

A. That is correct.

* * * * * * *

Cross-examination.

By Mr. Kleinfeld:

Q. Dr. Vos, I think you testified in answer to Mr. Markel's questioning that you were not familiar with the [fol. 364] particular levels which might be used in a particular food, is that correct?

[244] A. Substantially so, yes.

Q. Now, did your answers to Mr. Markel change your opinion as to whether FD&C Red No. 32 was a harmless coal-tar color?

A. No, it did not.

Q. Did the questioning and your answers change your opinon as to whether Orange No. 2 was a harmless coal-tar color?

A. No.

Q. Mr. Holloway asked you questions about whether almost any substance might not cause some adverse reactions, for example, salt, and I think you said that if sufficient quantities, even salt might produce some adverse physiological reactions, is that correct?

A. That is correct.

Q. Let's take some other substances. For example, will you consider carbolic acid a harmless substance?

A. No, I would not.

Q. Could I possibly use such an infinitesimal portion of carbolic acid in a food so that no one would be injured by eating that food?

A. I am uncertain as to what amount of carbolic acid can be added to food without causing injury to any persons. There is animal information on the toxicity of carbolic acid, however.

Q. Is it conceivable you might use such an infinitesimal amount of carbolic acid or strychnine in a food so that a [245] person eating that particular food would not be injured in any respect?

. . . . . .

[fol. 365] Q. Dr. Vos, if we assume that a substance like strychnine or carbolic acid might be used in a food in such a minute amount as not to cause injury to a person eating that particular food, would that change your opinion as to whether carbolic acid or strychnine was a harmless substance?

A. No, it would not.

[246] Q. Would your opinion still be the same that carbolic acid, for example, was a harmful substance, even though a certain slight percentage might be used in a particular food so as not to cause harm in a person consuming it?

. . . . . .

Dr. Smith: My name is William E. Smith. I am Associate Professor of Industrial Medicine at New York University, Secretary of the Cancer Prevention Committee in New York, Chairman of the Committee on Cancer Prevention for the International Union against Cancer.

I am here in connection with my service on these two committees. I believe it may be pertinent to make some mention of their composition to establish the substantial nature of their interest in the hearings.

. . . . . .

[247] By Dr. Smith:

Q. The first is: If he could give us any indication of the possible extent of the problem that he has been—the practical extent of the problem he has been studying, in that we would be interested in learning the amount of [fol. 366] the dyes that are the subject of this hearing that have been certified by the Government for use in foods within the past few years.

I should also like to submit, if you wish to accept, a copy of the proceedings of the Cancer Prevention Committee which was published as a special issue of the A.M.A. Archives of Industrial Hygiene and Occupational Medicine in 1952.

* * * * * * *

[248] Q. My next question refers to the tests that the witness has described for cancer producing action of the dyes. I note that on page 71 of the proceedings of the Cancer Prevention Committee, a copy of which I am prepared to submit, reference is made to tumors of the liver produced by a dye described——

Mr. Holloway: I must object to that.

* * * * * * *

[249] Q. Whether the witness for the Government feels that the studies that he has described on the tests for possible cancer-producing action of these dyes constitute, in his mind, full [250] and satisfactory evidence for the absence of such activity on the part of these dyes, and I ask the question in view of findings in the literature——

* * * * * * *

The Witness: I would say that the experiments which we have conducted are not complete with respect to the question of whether the three coal-tar colors under con- [fol. 367] sideration are capable of producing cancer under any circumstances.

* * * * * * *

[252] By Mr. Holloway:

Q. Dr. Vos, aren't the amount and method of proposed [253] use of a material necessary data for deciding whether the material is harmless for the use intended?

A. May I hear that question again, please?

(Question read.)

The Witness: I would say yes.

. . . . . .

[255] Presiding Officer Hardy: Will the witness explain how he used "harmless" on the witness stand? In what manner did you use the term "harmless", in a pharmalogical sense, or as a conclusion of law under the Food and Drug Act?

The Witness: I used it in pharmalogical sense.

Presiding Office Hardy: That is the way you used it all through your testimony, is that correct?

The Witness: That is right.

. . . . . .

[fol. 368] [256] Q. The purpose of my question is to see what the witness' understanding of the question was, so I think the only question addressed to the witness is, how did you understand Mr. Holloway's question? What was the meaning of your answer?

Presiding Officer Hardy: I think we are just likely to get more involved. I suggest, Dr. Vos, you answer Mr. Holloway's question, and anybody that wants to clear it up on further cross-examination or further direct will be given the opportunity. You have heard Mr. Holloway's question. I think you made an answer. Is that the answer you desire to make to his questions, is that still the answer.

[257] The Witness: Yes. The amount of the dye, of the color, has to be considered in determining whether or not it is harmless.

. . . . . .

[258] Re-Cross Examination.

By Mr. Holloway:

Q. You use a substance in several ways. You apply it to the skin, you take it internally, you gargle with it, you use various methods of application?

Presiding Officer Hardy: With that explanation in mind, Dr. Vos, can you answer his question?

The Witness: I think it is appropriate the method of use should be taken into consideration. The dyes in question [fol. 369] are at present being certified for use in foods, drugs, and cosmetics, and the data which we presented in these exhibits have shown that they are not harmless for use in all of those products. As I have pointed out, we have no data as to whether they are or are not harmless for external application.

. . . . . .

[259] Q. Doctor, I think you can see inherent—you have indicated, I think you can see an inherent good in your answer, since you state that you have made no experiments or have no experience for the use of the subject colors in cosmetics, or for application to the skin. And then at the same time you imply that your experiments have indicated to you that the application of the colors to the skin are not harmless.

. . . . . .

Q. In view of that, will you please explain your answer?

A. I don't recognize the ambiguity which you refer to. As I see it, these drugs, these colors are, as I say, at present certified for use in foods, drugs and cosmetics, and the proposal is to withdraw them from certification for those three purposes, and the evidence shows that the colors are not harmless under certain conditions. The question of whether they are harmless under certain other specified conditions, namely for external application, is as yet unanswered.

. . . . . .

[260] A. My opinion as to harmlessness does not apply to external application. In other words, I have no opinion as to the harmlessness of these colors by external application.

Q. Would you include in external, the lips?

[fol. 370] A. Well, I believe it is commonly recognized that colors which are applied to the lips are to a greater or lesser extent swallowed, which is the route of administration by which these colors were found to be not harmless.

* * * * * * * *

Q. Doctor, I am trying to get straight in my own mind, perhaps it may help others, whether we are talking about a harmless substance or a harmless amount of a substance. It seems to me they may be quite different things. For example, you have testified that in your opinion, based on your training and experience, and on the data which you have submitted here, FD&C Red No. 32 was not a harmless coal-tar color, is that correct?

A. That is correct.

Q. Now would your opinion be changed if an amount of Red [261] No. 32 was used in or on a particular food product in an amount less than those amounts which you utilized in your experimental work? If you use a lesser amount than the amounts used in your experimental work, and for example, you did not and could not observe any deleterious or harmful effects in a person or a test animal, in testing the food with the smaller amounts of Red 32, would you then say, in your opinion, Red 32 was a harmless coal-tar color?

A. No, I would still regard it as a harmful color on the basis of the tests which we have conducted.

Q. Isn't there any difference from the viewpoint of pharmacologists and toxicologists between a harmless substance and a harmless amount of a substance?

A. That is correct.

* * * * * * * *

[fol. 371] [262] By Mr. Markel:

Q. Can you tell us in what sense you have used the term harmless, by defining the term?

A. I have said that these colors are not harmless in the

sense that they did cause harm to the experimental animals in the experiments which are listed here.

Q. And in answer to one of my questions also, you have no evidence it would cause harmful effects in quantities used under ordinary conditions of use?

A. With the exception of the——

[263] Q. Candy incident——

A. Candy incident.

. . . . . .

Re-direct examination.

By Mr. Steffy:

Q. Doctor, you have asked concerning the term milligram per kilogram, and how you converted it to grams per millions. In the experiments reported in Exhibits 2 to 4, is it true where you use the term milligram per kilogram, that the substance upon which you were reporting was given in capsule form at those times?

A. Well, it was given by several routes of administration. In many instances it was given in capsule form; in some cases it was given by stomach tube, as an oil solution. In other instances it was injected. Milligrams per kilogram refers to milligrams per kilogram of body weight of the animal.

Q. Then where you use milligrams per kilogram, it was not given in the diet but was given separately, is that correct?

[fol. 372] A. That is correct.

Q. Where you used parts per million, that is where the substance was included in the diet as a whole?

A. Where we said parts per million, or percent of the [264] diet, that is where the substance was included in the diet.

Q. In your opinion, Doctor, do the experiments reported in Exhibits 2 to 4 show a possibility of harmful effect upon humans of the coal-tar colors used in those experiments?

A. There is certainly a possibility. As to how great a possibility there is, it is a matter of speculation, I would say.

Q. Do you have any evidence to show that FD&C Orange 1, or Orange 2, or Red 32, are harmless when applied topically?

A. No, I do not.

Q. On cross examination you were also asked concerning the toxicity of carbolic acid. I believe you stated that you know generally the level of chronic toxicity of carbolic acid on certain animals, is that correct?

A. That is correct.

Q. Could you give an approximation of the comparison of the chronic toxicity of Red 32 with carbolic acid?

A. Carbolic acid is tolerated in the—

. . . . . .

[265] Mr. Kleinfeld: The point is, it seems to me we are trying to establish whether a particular substance, let's say Red 32, is or is not a harmless substance. Now unless you can go to the dictionary and use that definition, when people [fol. 373] brought in substances like salt, it seems to me perhaps the best way of determining from a pharmacologist viewpoint whether a substance is harmless or not, how it compares in toxicity wi comparable substances. I can't think of a better way, myself.

. . . . . .

[266] The Witness: From the standpoint of chronic toxicity, when administered in the diet of rats, carbolic acid is tolerated without adverse effects at concentration of 1 or 2 per cent. On the other hand, Red 32, as shown in these experiments, had an adverse effect on growth and survival at concentrations of 1/10 of 1 percent, or greater.

. . . . . .

[272] Q. Well now, your answers have already brought out that the LD-50, the 22 substances is quite different. It is much higher for Red 32, by that meaning much less, it takes much more of Red 32 to produce comparable effect than it does carbolic acid, isn't that true?

A. By single administration that is right—by oral administration.

Q. By single administration?

A. That is correct.

Q. And on repeated feeding the animal tolerates much more carbolic acid?

A. That is correct.

Q. How can you make a comparison?

[fol. 374] A. Well, there are several types of toxicity. There is acute toxicity and there is chronic toxicity. One substance, "A", can be more toxic than "B" acutely, but chronically, it can be reversed. That is the situation you have here.

Q. But nevertheless you can take column 2 and 2, and get 4 out of it. In other words, nevertheless you feel you can make those comparisons, notwithstanding the differences?

A. Well, I believe that both types of toxicity have to be taken into consideration. If the thing is acutely toxic, it is certainly not harmless. If it is chronically toxic, it is also [273] certainly not harmless.

. . . . . .

[274] The Witness: Edwin L. Gustus. I am here today representing the Bjorksten Research Foundation of Madison, Wisconsin. Should I give my background?

Presiding Officer Hardy: Give a brief summary of your qualifications, Doctor.

The Witness: I was graduated in Chemistry from Stanford University in 1921, following which I took a Master of Science Degree in Northwestern University, and taught in the Medical School there for two years in the biochemistry department.

Subsequently, I took a Doctor of Philosophy Degree in organic chemistry at Northwestern University, and then served five years on the Rockefeller staff of Medical [fol. 375] Research in the Department of Pharmacology. Subsequently, I went to Europe as an International Education Fellow, and studied with Professor Ruzicka, the Nobel Prize Winner, at the Swiss Technical Institute. I then returned to the United States to the Pennsylvania State University. Subsequently again a guest [275] worker at the Rockefeller Institute for Medical Research, and then subsequently to that I have been bio-chemist in the drug industry with two firms.

I am not a physician, and I am not strictly speaking a pharmacologist. The statement I have to read this afternoon is a broad one and not specific particularly to

the dyes that we have discussed, but to dyes in general belonging to these groups.

. . . . . .

[276] over this statement, that appears to be a statement of general conclusions based on rather—apparently rather extensive investigation of literatures and what not, and affects the whole chemical industry, not only all the difficulties here but it cuts clear across the board of this whole question which is at the moment highly controversial. As much as I regret to object to statements made by people who come in and want to make statements, but because of its character I must object unless all the underlying data on which these conclusions were based is produced here as a basis for this statement, and if need be I am perfectly willing to consent to a recess of sufficient proportion so that the doctor can get his material together, but I feel that it is not fair to the whole industry, not only the industry which I represent, but other industries, to put such general conclusions in a record of this character, without backing them up.

[fol. 376] Presiding Officer Hardy: Mr. Markel, I believe the statement is relative. The weight to be given it is entirely a different question. The lack of foundation or experimental data would go certainly to the weight to be given the statement. But I believe—Doctor, let me ask you one or two questions.

What is the Bjorksten Research Foundation?

The Witness: It is a foundation supported by private funds, and is dedicated to the investigation of certain bio-chemical phenomena, associated with age. We have up to date [277] been studying the deposition of cholesterol in the arteries, largely with the idea of trying to obtain some insight in the changes which occur in the arteries with aging, but in going through our literature studies we have become aware of the fact that substances occur in the diet of man which may not be in the diet of experimental animals, and that it might be worth our while to consider—

. . . . . .

[278] The Witness: Workers at the Bjorksten Research Foundation have recently been engaged in reviewing the

literature on biochemical processes which may be involved in the various manifestations of human aging. Our attention has been attracted to the effects which chemical substances, commonly added to food materials or likely to contaminate food products, may have on such processes. We are very much aware of the paucity of reliable experimental evidence on the effects of very long continued ingestion of certain of these additives and the [fol. 377] difficulty of translating results from animal experiments to the question of human health.

Among those chemical substancies in this group which are purposefully added to foods, we feel that the certified coal tar dyes deserve a great deal of further study and that their harmlessness over the very long term may well be questioned.

We feel that there is a great difference between a material which the public can avoid by the exercise of free choice and one which necessarily finds its way into the daily diet of a [279] great majority of the population. It is this inability of the public to avoid by choice the ingestion of certified food dyes that makes the question of their harmlessness over many years of daily ingestion one of the most important tasks which come within the responsibilities of the Food and Drug Administration. It is imperative that the public, and not the food dyes, be given the benefit of any doubt.

In recognizing that this right of choice is effectively denied to the consumer, dyes which have found their way to the certified list should not be allowed to remain there if any reasonable doubt, however slight, exists about their long term harmlessness.

We are exceedingly happy to see that the Division of Pharmacology of the Food and Drug Administration is giving much attention to this question and we feel that their request that certain dyes be eliminated from the certified list is decidedly in the public interest. We hope that these investigations of certified food dyes w-ll be continued and extended to include those dyes frequently used for coloring foods of general daily use. Such dyes should be given the most careful and prolonged study, especially in regard to their possible cumulative effects, and they [fol. 378] should be promptly removed from the certified

list if there is found to be the slightest reason to doubt their harmlessness over a lifetime of daily ingestion.

. . . . . .

[280] Cross-examination.

By Mr. Markel:

. . . . . .

Q. If I suggest to you the dye manufacturers operate exactly as you suggest, that if there is any question about harmfulness, they stop making and stop merchandising. I am suggesting that to you. Do you have any information to the contrary?

A. No. I only know the harmlessness of certain dyes was as far as I am concerned amply demonstrated by the testimony here today. I hope, therefore, that the dye manufacturers will indeed follow the thing which you say is their principle.

[287] The Witness: My name is Robert C. Evans. I am General Manager of the Florida Citrus Commission, with headquarters at Lakeland, Florida.

. . . . . .

[290] The Witness: The Florida Citrus Commission has interested itself in this hearing because we understand that one of the colors here under consideration, Red 32, is the principal color used in coloring oranges. Therefore, the Commission, at a meeting held January 6, directed that I and its Director of Research, Dr. L. G. MacDowell, appear [fol. 379] at this hearing and present certain factual data, that may be helpful to the Food and Drug Administration.

I wish to state that our appearance here is not to be construed that the Commission opposes any action which the Secretary may deem advisable on the basis of the record of this hearing. Neither are we appearing to take a position for [291] or against the artificial coloring of oranges because it is our understanding from the notice of the hearing in the Federal Register that the merits of coloring oranges or not coloring oranges are not involved in this hearing.

. . . . . .

[293] Direct examination.

Presiding Officer Hardy: Will you state your full name?
The Witness: Louis Gardner MacDowell.
Presiding Officer Hardy: You are also—
The Witness: I am Research Director of the Florida Citrus Commission, Lakeland, Florida.

. . . . . .

[295] The Witness: This report was prepared by Dr. S. C. [296] Ting, a Research fellow of the Florida Citrus Commission, and directed to myself. The work was done at my direction.

[fol. 380] To save time in the testimony I would prefer to skip over the thing fairly rapidly and start out by saying that under sampling that two boxes of color-added pineapple oranges, size 216, were obtained from a commercial packing house in Hope County, Florida, that is, and all analyses in this report are based on these fruits. . .

. . . . . .

Reading from page 12, Table 9, a summary table on the concentration of dye on color-added oranges and in products made from color-added oranges, we find that whole fruit analyzed by extraction and chromatographic separation ranged from 3.39 to 4.69 parts per million of dye per fruit. Whole fruit by a chloroform washing method, which is outlined in the procedure, ranged from 4.96 to 6.78 parts per million. Peel of fresh fruit by the extraction and chromatographic separation, ranged from 17.63 to 24.39 parts per million. Peel of fresh fruit analyzed by the chloroform washing method analyzed from 25.79 to 34.26 parts per million. Juice extracted from whole fruit which had been color-added, and extracted on two types of commercial extractors, ranged from .04 to .07 parts per million of dye.

Candied orange peel analyzed 7.4 parts per million. [297] And orange marmalade analyzed 1.8 parts per million.

. . . . . .

[322] Will you state your name?
The Witness: C. Boyd Shaffer.

[fol. 381] Direct Examination.

By Mr. Markel:

Q. What is your occupation, Mr. Shaffer?

A. I am Chief Industrial Toxicologist of the American Cyanamid Company.

Q. Is that company a manufacturer of one or more of the colors here under consideration?

A. They are.

Q. Has the industry, the coal-tar color industry, organized a committee for the purpose of considering the problems raised by the consideration of the coal-tar colors listed in the notice of this hearing?

A. Yes, they have organized such a committee, and I am chairman of that committee.

Q. How many manufacturers does the committee speak for?

A. The committee speaks for nine basic manufacturers of coal-tar colors. That constitutes the entire industry.

[323] Q. Now, you have indicated you would like to make a statement for the record as Chairman of this Committee. Will you proceed to make that statement?

A. I might say at the outset that the coal-tar color industry has conducted no further pharmacological investigations of these colors since they were admitted to the list for certification in 1938. When certain experimental data was called to our attention last year by officials of the Food and Drug Administration there did not remain sufficient time for use to undertake any further investigations of our own. That circumstance will explain the fact that we have no—the industry has no pharmacological data of its own to submit at this hearing.

[fol. 382] It was the judgment of the Committee that if any doubt existed as to the potentiality or harm of these colors, that the primary manufacturers would refrain from submitting further batches of these colors for certification. Therefore, the primary manufacturers have ceased submitting any further batches of the 3 colors in question for certification with the exception that we are submitting, and shall continue to submit so long as it remains certifiable, FD&C Red No. 32 for the sole purpose of the coloring of oranges. There is no sale at present of Red 32 for any other purpose.

Q. May I interrupt at that point? Have the interested members of the industry given written assurances to that effect [324] to the Food and Drug Administration?

A. The American Cyanamid Co., which is my employer, has written the Food and Drug Administration that we have discontinued the sale of Red No. 32 for any other purpose but the coloring of oranges, and insofar as the other manufacturers are concerned, I have by word of mouth, assurance that they are not selling the color for any other purpose. I do not know that such intention was expressed in writing to the Food and Drug Administration.

The reason that we continue to sell FD&C Red No. 32 for the coloring of oranges is that having the knowledge of the amount and distribution of the color in the fruit, and in products prepared from the fruit, we believe that human consumption is negligible.

. . . . . .

[fol 383] [325] Q. You said, Dr., some months ago, when your Committee was informed, the Food and Drug Administration advised you that these three colors were in question as to their toxicity?

A. Yes, sir.

. . . . . .

By Mr. Kleinfeld:

Q. Dr. Shaffer, has your company conducted any pharma--logical work on the 3 colors which are at issue here?

A. We have conducted pharma--logical work on FD&C Red No. 32.

Q. When did you perform that work?

[326] A. It was done in 1938.

Q. Have you done any work since then?

A. We did a 90-day feeding study of the dye, in 1952.

Q. Did you bring with you the data?

A. No, sir, I did not.

Q. Is there any reason why you didn't?

A. There is no reason why I did not.

Q. You performed no additional work since that particular type of work which you just mentioned, is that right?

A. That is correct. There was no additional work.

Q. Do you know whether——

A. I might say, Mr. Kleinfeld, we regard that small amount of work, the 90-day feeding study, as rather insufficient to establish the point one way or the other. That is why I neglected that, in saying to all intents and purposes, we have done no further pharmacological work.

Q. Why did you perform it?

A. Why did we?

[fol. 384] Q. Yes.

A. We intended to carry out, it was the first step in the program of more extensive studies, but with the data developed by the Food and Drug Administration we saw no reason to complete further studies, or to undertake further studies.

Q. Are you willing to accept the result of the studies made by the Food and Drug Administration?

[327] A. Yes, we do.

Q. Do you know whether any of the other companies, comprised in your Committee, whether they have done any pharmacological work on these 3 colors?

A. They have not since 1939. I am quite confident about that.

Q. Has the American Cyanamid Company performed any independent work in trying to discover how much of these colors is found in various foods, including oranges and products made from orange peel, on which these colors may have been employed?

A. No, sir, we have not.

* * * * * * *

EXHIBIT 3

Chronic Toxicity of FD&C Orange No. 2 In Rats

(1939)

In a two-year experiment 24 rats, including both sexes, were fed 500 ppm FD&C Orange No. 2 mixed in a diet called "Diet A." This diet consisted of natural foodstuffs such as whole cer-al grains, leguminous seeds and milk solids, fortified by the addition of mineral constituents and accessory food factors required by the rat for adequate growth. [fol. 385] A second group of 24 rats received the same diet

without added color and served as controls. In a parallel two-year experiment two groups of 18 rats, of both sexes, each were fed 500 ppm and 100 ppm respectively, of FD&C Orange No. 2 mixed in a low-protein diet. This diet consisted of 72% starch, 6% casein, 6% corn oil, 5% yeast, 5% whole liver powder, 4% salt mixture and 2% cod liver oil. A third group of 18 rats received this low-protein diet without added color and served as controls for this experiment.

The growth data and the original mortality data on these two experiments have been discarded, but adequate mortality data was taken from the pathologist's files. There was no effect on mortality, survival of the two-year experiment being 9 of 24 for the Diet A controls and the same number for the treated rats; 6 of 18 for the low-protein diet controls, 8 of 18 for those fed 500 ppm dye, and 6 of 18 for those fed 100 ppm.

Department of Health, Education and Welfare

Exhibit No. 3.

Hearing FDC-60.

Offered by: Government.

Date 1/19/54.

Reporter TWB.

[fol. 386] Gross and relatively detailed microscopic pathological examination was done on the above animals as follows:

	Number Started	Not Rec'd	Gross and Micr. Exam.	Gross Exam. Only
Diet A controls	24	2	21	1
Diet A, 500 ppm	24	2	21	1
Low protein Control	18	0	15	3
Low Protein 500 ppm	18	3	12	3
Low protein 100 ppm	18	1	13	4

The low-protein diet caused such lesions as fatty change in the liver, and hairballs in the stomach, in both control and treated animals. Because most of the animals were 1½ to 2 years of age, the animals on both diets showed a number of tumors and other incidental lesions such as slight bile duct proliferation in the liver, nephritis, testicular

atrophy, etc. Only in the heart could a definite difference between treated and control animals be made out. Right ventricular hypertrophy was seen either grossly or microscopically (usually both) in 6 of the rats on 500 ppm in Diet A, in 7 of those on the same level in the low-protein diet, in 2 at 100 ppm, and in none of either control group. The 2 instances at 100 ppm were slight in degree, whereas those at 500 ppm averaged moderate. By themselves the 2 instances at 100 ppm could not be called significant. The livers of the 500 ppm group on diet A had suggestively more of the common slight old-age changes, especially bile duct proliferation, then did the controls; in the low-protein group any effect of the color was obscured by that of the diet. [fol. 387] Also, this same 500 ppm Diet A group showed 3 instances of slight hepatic cell hypertrophy or hyperplasia, which changes were not noted in any of the other groups.

Chronic Oral Toxicity of FD&C Orange No. 2 in Rats

(1940)

Method: Five male and 5 female rats were fed a ground commercial animal laboratory diet to which FD&C Orange No. 2 was added. For the first 8 weeks of the experiment, the concentration in the diet was 0.1%. It was then increased to 0.2% for the remainder of the experiment. The rats were 21 or 22 days old at the start and weighed from 25 to 50 grams. They were housed in individual cages, given free access to food and water, and were weighed at weekly intervals. This experiment was conducted simultaneously with the 1940 test on FD&C Red No. 32 and the same group of control rats served for both experiments. The results on these control animals are repeated here to facilitate comparison.

Results: As shown in Table 1 the addition of 0.1% FD&C Orange No. 2 to the diet of rats markedly depressed their growth. When the level was increased to 0.2%, deaths began to occur. Seven of the rats were found dead between the 9th and 22nd week of the experiment; 3 were sacrificed because of poor condition between the 13th and 17th week. Seven of the 10 control rats survived to the end of the experiment. (101 or 102 weeks.)

Gross and microscopic pathological examination was made of 6 treated and 5 control animals, and only gross examina-

tion of 3 additional treated and 4 additional control animals. (The controls also were controls for FD&C Red No. [fol. 388] 32.) The treated rats had been on the experiment for 10 weeks to 5 months, and the controls for 46 weeks to 2 years. The liver was markedly affected in the treated rats, whereas the control livers were almost unaffected. Grossly, the control livers showed no abnormalities, whereas 5 of the 9 treated ones did. There were 3 instances of yellow or red mottling, 1 of pallor, and 1 of slight enlargement. Microscopically, the total changes in the 5 controls examined were 1 instance of slight diffuse atrophy and 1 of slight hepatitis. In the 6 treated animals which were sectioned, all livers showed either focal coagulation necrosis, a more diffuse subacute type of degeneration, or both. The total process was marked in degree in 4, moderate in 1, and slight in 1.

Table 1

Weight and Mortality of Rats Fed a Diet Containing FD&C Orange No. 2

Dosage	Sex	No. of Rats	Weight, gm Initial	Weight, gm 8 Weeks	Medium Survival Time Weeks
0%*	M	4	39	365)	101
	F	5**	33	216)	
0.1% for 8 weeks	M	5	35	140)	15½
0.2% thereafter	F	5	42	122)	

* These are the same control animals reported in the the 1940 FD&C Red No. 32 experiment.

** Data sheet on one female rat is missing.

[fol. 389] Subacute Oral Toxicity of FD&C Orange No. 2 in Rats

(1952)

Method: Male weanling rats of the Cabern-Mendel strain weighing between 45 and 55 grams were fed 0.1% and 0.25% of FD&C Orange No. 2 in a basic diet of commercial ground laboratory chow for a total of 42 days. Ten rats were fed the higher level while five each were fed 0.1% and control basic diet without the color.

Rats were caged individually, allowed free access to food and water and weight gains and feed intake were recorded once during each week of the experiment.

Results: The data given in Table 1 show that FD&C Orange No. 2 retarded growth severely when fed at 0.25% and markedly when at 0.1% in the diet. Weight gains are given for 35th day because controls lost weight during the last week when their food cups were not filled. The higher level produced death of 20% of the animals by the third week and 40% by the fifth week. It became apparent that animals could not tolerate 0.25% of the color and the experiment was terminated on the 42nd day.

Table 1

Weight and Mortality of Rats Fed FD&C Oranges No. 2

	Sex	No. of Rats	Average Initial Weight gm.	No. of Rats	Average on 35th Day Weight gms.	Average on 35th Day Wgt Gain gms.	Mortality 42 Days
Control	M	5	43	5	202	159	0%
0.25%	M	10	50	8	74	24	40%
0.1%	M	5	47	5	130	83	0%

[fol. 390] Test of FD&C Orange No. 2 For Carcinogenicity by Repeated Subcutaneous Injection in Rats

(1953)

Method: Nine male and 9 female (7-week old) rats were injected subcutaneously once a week with 0.1 ml. of a 5% w/w suspension of FD&C Orange No. 2 in glycerin. Nine males and 9 females which were litter mates of the above rats were similarly injected with glycerin alone and served as controls for both this experiment and the second experiment of this type on FD&C Red No. 32.

Results: As shown in Table 1 the weekly injection of approximately 5 mg. of FD&C Orange No. 2 depressed the growth of the rats. One of the treated rats died following 7 injections; a second died after 8 injections and the injections were discontinued. A third rat was found dead 11 days after the final injection of FD&C Orange No. 2. There were no deaths among the control animals. Since the experiment was discontinued after 8 injections because of toxic effects no conclusion was reached as to the possible carcinogenic action of the color.

[fol. 391] Table 1

Weights of Rats Injected with a Glycerin Suspension of FD&C Orange No. 2 or with Glycerin

Injection	No. of Rats	Sex	Average Weight—Gm. Initial	5 weeks	8 weeks
FD&C Orange No. 2	9	M	196	295	300**
	9	F	147	187	195**
Glycerin*	9	M	193	335	384
	9	F	145	203	222

* These rats are the same ones which served as controls in the similar experiment on FD&C Red No. 32.

** Average of eight survivors.

Carcinogenicity Tests in Mice With FD&C Orange No. 2

(1940)

The color was made into a glycerin paste and inserted by means of a modified trocar into the right axillary region subcutaneously of 18 C-57 black mice (8 males and 10 females #181-198) and of 18 swiss white mice (18 males #199-216). Each mouse received 12.1 milligrams of the color each injection. The first injection was made 10-3-40 and 10-8-40 for the two groups respectively and repeated 8, 19, 24, 30, and 55 weeks thereafter except for the C-57 group which did not receive the 55-week injection. The remaining 5 mice in this group had been autopsied 39 weeks after the first injection. No tumors were seen at autopsy by gross examination.

[fol. 392] A similar set of control mice was used. See FD&C Red No. 32.

Chronic Oral Toxicity of FD&C Orange No. 2 in Dogs

(1938-1944)

Method: In this experiment two dogs received FD&C Orange No. 2 in gelatin capsules daily except Sunday. The first dog, a male, received the dry color in the capsules at a dose of 20 mg. per kg. per day for 60 months. It had previously received 100 mg. per kg. per day for about 11 months. The second dog, a female, received a dose of 5 mg. per kg. per day of the color dissolved in oil and placed in capsules for 62 months. It had previously received doses

of 100 mg. per kg. as an oil solution administered by stomach tube daily for about a month, followed, after a rest period, by doses of 20 mg. per kg. per day administered as an oil solution in capsules for about a month.

Results: The 100 mg. per kg. per day dose of the male dog was discontinued because the dog was in poor condition. When the dose was reduced to 20 mg. per kg. per day after an approximate one-month rest period the color was tolerated and the dog gained weight. It was sacrificed in good condition after 60 months on this dose. The dose of the female dog was reduced from 100 mg. per kg. per day to 20 mg. per kg. per day and finally to 5 mg. per kg. per day because the dog did not eat well and was gaining weight s' vly on the higher doses. The 5 mg. per kg. per day dose w.s tolerated and the dog was sacrificed in good condition [fol. 393] after 62 months on this dose. In this period it had six litters of puppies which were of average size and health.

Following sacrifice these two dogs were examined grossly and in relative detail microscopically. They were normal for their age except that the testie and prostate of the 20 mg. dog were moderately atrophic. Since no other dogs at this dosage level were available for examination no significance can be attached to the observation.

Chronic Oral Toxicity of FD&C Orange No. 2 in Dogs

(1953)

Method: This color was fed at levels of 0.2% and 0.04% in the diet. A basic diet of ground laboratory chow was used. Each dog was housed in an individual metabolism cage, fed and watered daily and given free access to his food. Each dog was weighed approximately weekly. A total of six young adult dogs evenly divided as to sex was used.

Results: The four dogs which were started on the diet containing 0.2% FD&C Orange No. 2 showed diarrhea which lasted for only a few (3-4) days. All ate poorly and lost weight steadily. On the 28th day of the experiment two of the dogs were sacrificed in extermis. They had lost respectively 43% and 32% of their initial weight. The remaining two dogs, which were in poor physical condition and had lost respectively 31% and 21% of their initial

weight, were placed on a normal diet for nine days. During this time they regained some weight and improved their physical condition. Along with two additional dogs they [fol. 394] were placed on a diet containing 0.04% FD&C Orange No. 2. On this level all four dogs did fairly well for about a month; following this they began to eat poorly and lose weight. On the 75th day the first of the four dogs was found dead. The second was found dead on the 95th day. The third was killed in extremis on the 98th day. The fourth was found just at death on the 124th day. All four dogs had lost approximately 50% of their body weight prior to death.

Pathological Changes in Dogs from Feeding of FD&C Orange No. 2

Path No.	Dog No.	Sex	Appr. Age, No.	% Dye in Diet	Days on Expt.	F.D.** or K.	Weight in Kg. Beg.	Weight in Kg. End
15710	B-6	F	34	0.20	27	K.	5.8	3.8
15711	105-263	M	9.5	0.20	27	K.	10.0	6.8
16032	M-302-2	F	15	0.04*	75*	F.D.	9.2	4.2
16097	M-293	M	35	0.04	95	F.D.	19.8	8.1
16118	105-264	F	11	0.04	98	K.	9.8	4.8
16352	M-305	M	26	0.04*	124*	F.D.	16.5	8.8

* After 27 days on 0.20%; weight during that time dropped from 11.7 to 8.0 kg. for 16032, and from 19.4 to 15.3 kg. for 16352.

** (Illegible) sacrificed because of poor condition.

Gross Pathology

15710—Marked emaciation; very little body fat. Viscera essentially negative. No worms.

15711—Slight to moderate emaciation. One to 2 dozen [fol. 395] roundworms up to 6 cm. long in upper portion of small intestine. Viscera essentially negative otherwise.

16032—Marked emaciation; moderate dehydration. No body fat. Liver firm and contains little blood; slightly atrophic and pale. Spleen pale red and bloodless. Uterus slightly distended; thin-walled. No worms. Bone marrow gelatinous. Thyroid pale. Tissues as a whole appear slightly anemic.

16097—Marked emaciation. Liver slightly atrophic, with a fine nutmeg appearance. Spleen pale and bloodless. No worms. Bone marrow somewhat gelatinous. Advanced post mortem autolysis.

16118—Marked emaciation. Tissues in general slightly anemic. Liver firm, medium brown color, slightly atrophic. Spleen purplish red. About 1 dozen roundworms up to 7 cm. long in uppor portion of small intestine. Bone marrow congested.

16352—Moderate emaciation. Peritoneal cavity contains about 100 cc. of clear, straw colored fluid; about 50 cc. of same in pleural cavities. Tissues in general appear anemic. Liver slightly atrophic, medium chocolate brown in color, slightly soft, and contains little blood. Kidneys slightly soft; dark tan color. Spleen bloodless; has a slight grayish tan tinge. No worms.

Microscopic Pathology

Because of advanced post mortem autolysis, microscopic examination of 16097 was limited to liver, kidney and bone marrow, including fat stains and smear respectively. From [fol. 396] each of the remaining 5 dogs, hematoxylin-sosin stained paraffin sections of formalin-fixed tissues were made from lung, heart, liver, gall bladder, spleen, pancreas, lymph nodes, kidney, adrenal, stomach (2), small intestine (3), colon, thyroid, parathyroid (except 15711), uninary bladder, voluntary muscle, testis (or ovary), prostate (or uterus), submaxillary salivary gland, and rib bone and marrow; also, from each of these 5 dogs frozen sections of kidney and liver were stained for fat with Oil Red O, a smear of bone marrow was stained with Giensa type stain, and paraffin sections were made of liver and kidney fixed in Zenker's fluid. Some adrenals were also stained for fat and/or had portions fixed in Zenker's fluid. All of those sections were normal or essentially so except as follows.

Atrophic Changes in Various Organs: This was the basic pathological pattern. For convenience, the most consistent and easily graded of these changes are shown in tabular form, and the degree of bodily emaciation is repeated. In the table, 1-slight, 2-moderate, and 3-marked or severe. The changes in the bone marrow and to a lessor extent in the spleen and lymph nodes, are a depletion of certain cells rather than actual shrinkage in size of the organ or of its component cells, but the term atrophy is often used and generally understood, and for convenience it is used here. In the skeletal muscles,

there were changes (nuclear multiplication, necrobiesis, necrobiosis), in addition to the atrophy, so that the total muscle lesion is a dystrophy rather than simple atrophy. Of the organs not listed, atrophic changes in the uterus were the most noticeable.

[fol. 397] The figures in the table have no mathematical exactness for comparative purposes because of subjective factors, differences in the atrophic process among various organs, and the difference between depletion and atrophy mentioned above. Because of the great liability of the bone marrow, a few words of explanation about it may help. Our dog rib marrows, on the average, normally are made up of (by inspection, not measurement) about 1/3 hematopaietic (plus a small percentage of stromal) cells, about ½ fat cells, and the remainder by, chiefly, capillary blood vessels. In determining these values the artefacts of shrinkage spaces, and the relative unobtrusiveness of fat cells in routine paraffin sections, have been considered. The moderate bone marrow depletion shown in the table means a reduction in hematopoictic cells of around 50% of the normal.

Pathology No.	Bodily Emaciation	Liver	Spl.	Lym.N.	Mar.	Tes.	Pro.	Muscle
15170	3	1-2	1-2	1	1-2	Fem.	Fem.	1
15711	1-2	0	0	0	±	2-3	3	±
16032	3	3	2	1	3	Fem.	Fem.	2
16097	3	2-3	N.S.	N.S.	2-3	N.S.	N.S.	N.S.
16118	3	±	2	1	±	Fem.	Fem.	1
16352	2	2	1-2	2	±Hy.	3	3	2

Abbreviations in last 6 columns mean respectively Spleen, Lymph Nodes, Marrow, Testis, Prostate, Female, Not Sectioned, and Hyperplastic.

Changes Other than Atrophy and/or Cellular Depletion: Stainable fat in the liver was shown to a very slight degree in 3 of the 6, the greater part of this being in [fol. 398] the Enpffer cells. In the kidney, stainable fat was greater in amount, but was within normal limits, the females showing more than the males as is commonly the case. Homosiderin in from very small to moderate amounts was present in the liver and bone marrow of the last 4 dogs in the tables. In the spleen, homosiderin was on the whole present in slightly greater than usual amount, but there was no relation of this

excess to dosage or duration. In the bone marrow, the nyeloid/erythroid ratio was determined only by inspection, not counting. In 16118 and 16352 it was reduced, appearing to be less than 1. In 15710 and 15711 it appeared slightly increased. Mature granulocytes were greatly reduced in 16097, 16118, and 16352. Atypical cells of apparent reticular derivation were noted in 15710, 16032, and 16352. The changes mentioned for this phase of the marrow examination indicate a definite effect of treatment on the marrow, but no consistent relation to time or dosage can be made. Certain changes in the skeletal muscles were previously mentioned; both these and the atrophy were greater in the thigh than in the neck muscles. Of the 5 stomachs sectioned, that of 16118 showed moderate enlargement and rarafaction of the fundis parietal cells.

The positive findings mentioned in the above paragraph can be attributed to treatment, as, of course, are the atrophies previously mentioned. Certain other changes, scattered among the various organs and none of major proportions, cannot be attributed to treatment; these are listed on the work sheets filed with the copy of this report in the pathology laboratory.

[fol. 399] Summary and Conclusions

Gross and microscopic pathological examination has been made of 6 dogs fed FD&C Orange No. 2 (Orange SS) at either 0.20% or 0.04% or both dosages, for periods of 27 to 151 days. Three of the dogs were found dead and the remaining 3 were sacrificed because of poor condition.

On gross examination, the only external change of significance was consistent emaciation, usually pronounced and varying from slight-moderate to severe. Internally, the common changes were slight atroph of the liver, and slight pallor (anemia) of the tissues in general. One dog had moderate amounts of fluid in the peritoneal and pleural cavities. Two dogs had intestinal worms.

Detailed microscopic examination was done on 5 of the 6 dogs, and some on the remaining one. The microscopic picture was consistent, the basic pattern being that of atrophy and/or cellular depletion in various organs, the

most frequently affected being liver, spleen, bone marrow, genital organs, skeletal muscle, and lymph nodes. In general, these atrophies paralleled the degree of emaciation. In addition, the changes attributable to treatment included dystrophic changes in skeletal muscle in addition to the atrophy there, changes in type and percentage distribution of bone marrow cells in addition to the depletion, slight hemoriderosis of the liver and bone marrow, a very small amount of fatty change in the liver, and, probably, changes in the mucosal cells in one stomach.

[fol. 400] On the whole, the effects from FD&C Orange No. 2 were very similar to those from FD&C Red No. 32, reported on January 4, 1954. Chemically the two dyes are also very similar, FD&C Red No. 32 having an additional methyl group on one of the rings.

Cathartic Action of FD&C Change No. 2 in Dogs

(1952)

Five of the eleven dogs which had been found to be sensitive to the cathartic action of FD&C Orange No. 1 was tested on FD&C Orange No. 2. In this test they were fasted over night. The next morning they were given a capsule containing 200 mg. of FD&C Orange No. 2. They were fed about 2 hours later. All five dogs developed diarrhea within eight hours from the administration of the capsules.

Exhibit 4

Chronic Toxicity of FD&C Red No. 32 in Rats

(1940)

Method: Five male and 5 female rats were fed a ground commercial animal diet to which 0.1% FD&C Red No. 32 was added. Four male and 6 female rats which received the basic diet served as controls. The rats were 21 or 22 days old at the start of the experiment and weighed from 28 to 51 grams. They were housed in individual cages, given free access to food and water, and were weighed at weekly intervals.

Results: As shown in Table 1 0.1% FD&C Red No. 32 markedly depressed the growth of the rats and reduced

[fol. 401] the median survival time. The last of the rats receiving the color was sacrificed in poor condition in the 58th week, while 7 of the 10 control rats survived to the end of the experiment (101 or 102 weeks).

Table 1

Weight and Mortality of Rats Fed a Diet Containing FD&C Red No. 32

Dosage	Sex	No. of Rats	Weight, gm. Initial	Weight, gm. 9 weeks	Median Survival Time, Weeks
0%	M	4	39	365	101
	F	5*	33	216	
0.1%	M	5	37	209	17
	F	5	34	121	

*Data sheet on one female rat is missing.

Department of Health, Education and Welfare.
Exhibit No. 4.
Hearing FDC-60.
Offered by: Government.
Date 1/19/54.
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[fol. 402] Chronic Toxicity of FD&C Red No. 32 in Rats

(1941)

Method: Nine male and 11 female rats, 21 or 22 days old and ranging in weight from 33 to 55 grams, were fed a ground commercial laboratory diet containing 0.1 FD&C Red No. 32. The rats were housed in individual cages, given free access to food and water, and were weighed at weekly intervals.

Results: As shown in Table 1, 0.1% FD&C Red No. 32 retarded the growth of these rats as compared with that commonly found in our laboratory on normal diet. The median survival time was 38 weeks. Of the 20 rats, 5 were found dead at intervals from the 18th to the 25th week, 12 were sacrificed because of poor condition at intervals from the 20th to the 71st week, and 3 were sacrificed to terminate the experiment at the 77th or 79th week.

Table 1

Weight of Rats Fed a Diet Containing FD&C Red No. 32

Dosage	Sex	No. of Rats	Weight, gm. Initial	8 weeks
0.1%	M	9	41	170
	F	11	42	145

Pathological Examination of Rats Fed FD&C Red No. 32, 0.1%

Gross and microscopic pathological examination was made of 10 treated animals from the two preceding experiments, and of 5 of their controls, with only gross examination being made of 1 more treated animal and 4 more [fol. 403] controls. The test rats had been on the experiment for 11 to 56 weeks, and the controls from 46 weeks to 2 years. The liver was definitely affected in the test as compared to the control rats, both grossly and microscopically. Grossly, the control livers showed no abnormalities, whereas 7 of the 11 treated ones showed either or both of varying degrees of a tan or nutmeg appearance, or in 1 instance was slightly rough. One of the 7 showed several nodules up to 7 x 7 x 5 mm. Microscopically, the total changes in the 5 controls examined were 1 instance of slight diffuse atrophy and 1 of slight hepatitis. In the 10 treated animals there were, by contrast, 6 instances of slight or moderate bile duct proliferation, 3 of slight hepatic cell hyperplasia irregularly mixed with areas of atrophy, 3 instances of moderate or marked centrolobular hepatic cell necrosis, 1 instance of hepatic cell hyperplasia which in places took the form of adenomatoid nodules mentioned in the gross description, and 1 instance each of slight and moderate fatty change. All 7 instances of hyperplasia and necrosis were in different animals.

Subacute Oral Toxicity of FD&C Red No. 32 in Rats

(1951)

Method: FD&C Red No. 32 was fed at various levels in a basic diet in an effort to determine this maximum tolerated dose. Five weanling male rats weighing 40 to 50 grams (average weight 45 gms.) were fed 2.0% FD&C Red No. 32 and 5 (average weight 46 gms.) were fed 1%. Five more

weanling males (average weight 47.9 gms.) were fed 0.5% FD&C Red No. 32. Later an additional 5 male rats several [fol. 404] days after weaning, weighing between 60 and 70 grams (average weight 65 gms.) were fed 0.5%. A fifth group (average weight 61 grams) was fed 0.25% FD&C Red No. 30 for 10 weeks.

Results: Rats fed at 2% died within 7 days. Those fed at 1% died within 12 days. Weanlings fed at 0.5% died within 21 days. Of the 5 slightly older rats fed 0.5%, 3 died within 26 days and the other two were sacrificed since weight was decreased below starting weight. Of the 5 rats fed 0.25% FD&C Red No. 32, 3 survived for 10 weeks and were sacrificed; 2 died at 7 and 6 weeks respectively.

Chronic Toxicity of FD&C Red No. 32 in Rats

(1952)

Methods: Groups of 24 weanling rats of our laboratory strain (Osborne-Mended) were fed levels of 0.25% and 0.1% of FD&C Red No. 32 in a basic diet of commercial ground laboratory feed. Equal numbers of males and females weighing between 40 and 50 grams were used in each group. Two groups, a total of 48 rats, were fed 0.25% of the color with the expectation that one of these groups could later be raised to a higher level. A third group received 0.1% of the color and the final group, which served as a control, was fed the basic diet. All animals were kept in individual raised cages and allowed free access to food and water. Animal weights and food intake were recorded weekly. Animals found dead but in good condition were opened for observation of gross pathology.

[fol. 405] Results: Inspection of average weight gains recorded in table 1 shows that FD&C Red No. 32 markedly retarded growth of rats at both levels fed. Mortality was strikingly increased at both levels in that all animals fed 0.25% were dead by the 20th week and 16 of 24 animals fed 0.1% were dead by the 26th week. Eight of the control animals are now living at the 109th week of the experiment. The intended raise of the color concentration in one group of 24 animals to a level higher than 0.25% was shown not to be feasible.

Of the 48 animals fed 0.25% 19 showed at autopsy liver damage or enlarged bile ducts or both. Their blood ap-

peared pale and watery. As a group they presented a picture of severe emaciation with complete absence of fat in carcass and viscera. Twelve of 24 animals fed 0.1% showed at autopsy large quantities of fluid in the chest cavity and presented a picture of emaciation and anemia.

The average values for hemoglobin and red blood cell counts taken on survivors at the 18th week of the experiment are shown in table 2 and bear out the general picture of severe to moderate anemia in the test animals as compared to the average of 10 animals of the control group.

[fol. 406]

Table 1

Weight and Mortality of Rats Fed Diets Containing FD&C Red No. 32

		Start		3 Months			12 Months			2 Months Mortality
Dosage	Sex	No. of Rats	Avg. Wgt.	No. of Rats	Avg. Wgt.	Wgt. Gain	No. of Rats	Avg. Wgt.	Wgt. Gain	
0%	M	12	46	12	386	340	12	505	459	0
	F	12	46	12	233	188	12	285	239	0
0.25%	M	24	46	13	120	84	0	—	—	100%
	F	24	45	11	103	57	0	—	—	100%
0.1%	M	12	45	10	256	211	2	450	405	75%
	F	12	44	11	174	130	2	195	151	58%

Table 2

Blood Changes in Rats Fed Diets Containing FD&C Red No. 32 (18 weeks on experiment).

Dosage	No. of Animals	Hemoglobin gm./100 ml	Red Cells per mm³	White Cells per mm³
0.25%	5	9.5	4,600,000	23,400
0.1%	10	12.3	7,450,000	24,560
0%	10	15.2	9,270,000	13,800

Pathological Changes in Rats from Feeding of FD&C Red No. 32

In the experiment for which the pathological changes are given in this paper, 48 weaning rats of both sexes were started on 0.25% of FD&C Red No. 32 (Oil Red XO in their diet. 24 others were put on 0.10%, and an additional 24 served as controls both for this dye and [fol. 407] for FD&C Red No. 4 (Ponceau SX). The rat numbers were 3991-4086, and the pathology numbers were 14770 for the first rat received and 16816 for the last.

Because of the relatively early deaths of most of the treated animals, not all were sent to the pathology laboratory. There were received 26 of the 48 on 0.25%, all of these 26 having died (20) or been sacrificed because of poor condition (6) after from 9 to 19 weeks of dye feeding. Of the 24 rats started on 0.10% of dye, 14 (8 found dead, 6 sacrificed because of poor condition) were received in the pathology laboratory after from 8 to 89 weeks' feeding; all but 3 of these 14 had been fed for 28 or fewer weeks, the 3 exceptions all being females that survived 51, 72 and 89 weeks respectively. No treated animals are still alive. Of the 24 controls, 8 are still alive at this writing (1-12-54), and of those not surviving, 1 found dead and 7 sacrificed because of poor condition have been received, after from 76 to 96 weeks on the experiment.

Gross Pathology

This portion of the pathological examination is, as customary, based on examination of the viscera fixed in 10% formalin before being sent to the pathology laboratory. In this instance the viscera were en bloc except for most of the older animals, in which they had been more or less cut apart. Rats fed 0.25% dye—The visceral masses were uniformly small for the ages of the animals, varying from slightly to markedly so, and on the whole were somewhat pale, the liver usually showing this best. Smallness of the individual organs was most apparent in [fol. 408] the case of the testes. The liver was not distinctly small. Five livers showed from very slight to slight-moderate rougness of the surface; one of these and 4 others showed very slight to moderate degrees of either a mottled or nutmeg appearance. The common bile duct was consistently enlarged; i.e., its diameter was greater than normal. Of the 26 ducts, one about 3 mm. in diameter was graded as markedly enlarged, 8 with a diameter of about 2 mm. were considered moderately enlarged, 2 were slightly to moderately enlarged (diameter about 1½ mm.), 6 were slightly enlarged (1 to 1½ mm.), 4 were questionably enlarged, and 5 were of normal diameter, not quite 1 mm. rats showed pneumonia in one form or

another, in one instance with pleuropericardial adhesions.

The rats fed 1.10% of the dye showed small and pale viscera, but to a lesser degree than at 0.25% Testicular atrophy varied from none to much. The liver was not disproportionate in size to the rest of the viscera, except for being small in the 2 oldest animals received. Six of the 14 livers had slightly rough surfaces, and 8 had a slight to marked degree of nutmeg appearance. None of the common bile ducts were enlarged, in contrast to the 0.25% group. However, again in contrast to the 0.25% group, in which no cardiac lesions were noted except for the one instance of pleuropericadial adhesions mentioned, nearly all of the animals on 0.10% showed one or more cardiac changes, the most common being right ventricular hypertrophy. This hypertrophy was present in 12 of the 14 hearts; one heart was not received, and that of the longest surviving animal was normal. The degree of the hypertrophy was slight in 5 and more [fol. 409] pronounced in 7 instances; 2 of the slight degrees were combined with dilation of the right ventricle. Enlargement of the right strium up to several times its usual volume was noted 7 times; whitish mural thrombi, whose average size was about that of a match head, were seen in the right ventricle of 4 hearts. Three rats showed pneumonia, 2 of these also having adhesions between lungs and heart.

The control rats, it should be remembered, were on the average much older than the treated animals, and therefore would normally show more of the usual spontaneous lesions that occur with advancing age in rats. Enlarged and granular kidneys were absent in the treated groups, but occurred in 4 of the 8 controls. Four livers showed a slight or moderate degree of nutmeg appearance, and one of these had a slightly rough surface and was very slightly enlarged; of the remaining 4 livers, 1 was slightly enlarged and 2 were slightly small. Only one heart was abnormal; its right strium was slightly and the right ventricle moderately dilated; hypertrophy could not be made out. Three animals had pneumonia. Three had tumors; these were respectively pulmonary lymphosareoma 1.6 x 0.7 x 0.7 cm.; perioscal lyphosarcoma 4½ x 3 x 2 cm.;

tumor in much of an 8 x 7 x 6 mm. adrenal; this last animal also having a 2 x 1½ x 1 cm. left tube-ovarian chronic abscess. The males had slight or moderate testicular atrophy.

Microscopic Examination

Of the 48 rats received, 29 were examined microscopically, 14 in detail and 15 with attention to only the major [fol. 410] structures of interest. The detailed list included lung, heart, liver, spleen, pancreas, stomach, small intestine, colon, kidney, adrenal, testis (oruterus and ovary), leg bones and bone marrow. All of the foregoing were sectioned for each of the 12 mentioned rats except that one leg was not received. In addition, sections for these 14 rats included 10 urinary bladders, 7 thyroids, 6 prostates, and 3 parathyroids. For the remaining 15 animals, sections included liver, kidney, heart, (in controls) lung, (in males) testis, and occasionally other structures such as tumor, etc. All the foregoing were hematoxylin-cosin stained paraffin sections. In addition, one liver was stained with periodic acid-Schiff and silver stains. The 29 sectioned animals included all 8 controls, 12 of the 14 on 0.10% dye, and 9 representative rats on 0.25%.

Liver: The livers of the treated animals showed a large number of changes which together made up a picture of, in every instance, moderate or marked liver damage in the 0.25% group, and very slight to moderate damage in the 0.10% group. It is difficult to give this process a single exact name. "Moderate to marked subacute degeneration" seems most applicable for the high dose animals, and "mild subacute degeneration and/or cirrhosis" for the low dose animals. The individual changes making up the composite lesion were enlarged, irregular hepatic cells, often in pseudoacinar formation; disorganization of the normal architecture; fibrosis; slight necrosis; increased variability of hepatic cell size; slight nonnuclear and less polymorphonuclear cellular infiltration; very slight bile duct proliferation; and, occasionally rounded nodules of hepatic cells with a proliferative appearance. The necrosis was of a [fol. 411] "nibbling" type, i.e., single cells or small clusters were affected, and not large clumps; also, the degree was probably underestimated at times when obscured by post mortem autolytic changes. The hepatic lesion in the 0.10%

animals was in part a reduction in degree of that in the 0.21% group, and in part it had a different appearance because of the following modifications. The pseudoacinar formations disappeared. Fibrosis was nearly as pronounced, but was concentrated in the centrolobular areas instead of being more diffuse. The occasional foci with a proliferative tendency were absent. The controlobular areas tended to become a mixture of capillaries, cellular infiltrate, loose fibrous tissue, and necrotic and dropping out hepatic cells; in other words, it could to some extent be called a cantrolobular cirrhosis. (Cirrhosis in the rat liver is not exclusively portal; see Ashburn et al., An. J. Path., 23,159, 1947). Two of the enlarged common bile ducts were sectioned and showed some epithelial proliferation.

The control livers showed 3 exceptional items, each in a different liver. These were (1) slight to moderate bile duct proliferation with preiductal fibrosis, (2) metastatic lymphosarocna cells in the sinusoids, and (3) an appearance not described in detail here but rather often seen in mouse livers and suggestive of chronic or residual hepatitis. Along with the first of these was moderate irregularity of architecture and moderate fatty change. In addition, because of the greater age of the control as compared to the treated animals, there were often seen the common slight liver changes of old rats. (In the following discussion, the previously mentioned unusual items are not considered. For example, there was as much bile duct proliferation [fol. 412] in the control as in the treated rats, but it should be remembered that bile duct proliferation is practically never seen spontantously in animals of the ages of the treated ones, and that in any event bile duct proliferation was a relatively minor feature of the hepatic lesion caused by dye feeding. Hepatic cell vacuolation interpreted as fatty change was of the same very slight degree throughout the different groups, but this is not considered a part of the changes caused by the dye. Very slight degrees of disarrangement of the normal architecture and of increased variability of cell size were present, as is often seen in old rats, whereas in the treated animals where these changes should have been even less noticeable they were much more pronounced, and were significant parts of the lesion. The important factors of large irregular hepatic cells, pasudo-

acinar formation, necrosis, and fibrosis with associated slight cellular infiltration, all significant parts of the lesion, were not present at all in the 8 controls with the exception of the 1 instance of a different sort of fibrosis as already mentioned.

Heart: With respect to the rats fed 0.10% dye, not a great deal can be added to what has been said under Gross Pathology. Of the 12 hearts grossly showing right ventricular hypertrophy, 11 were sectioned. In those, hypertrophy of the right ventricle was graded as moderate in 7, slight-moderate in 2, slight in 2. In addition to the 4 right ventricular thrombi noted grossly, 2 smaller ones in the same location were seen in the microscopic sections. (Apical clotted blood is not picked out at gross examination for fear of dislodging such thrombi.) All 6 thrombi showed more or less organization and calcification. The right [fol. 413] strium showed hpertrophy as well as dilation. No left ventricular or atrial hypertrophy was seen. Myocarditis and myocardial fibrosis were present in 6 hearts in slight or very slight degree except for one heart in which the process was severe. It was more pronounced in the right than on the left. Since the valves are cut less consistently than the other structures, no exact figures can be given for the valvular thickening with low grade inflammation which was seen in a few hearts; it affected the right A-V valve most, then the left A-V, and apparently not the others. Pericarditis accompanied the 2 instances of pleuropericardial adhesions.

In the 0.24% animals, all 9 hearts sectioned were normal except for pericarditis accompanying pleuropericardial adhesions in one instance, and for pyemic foci in another animal in which several organs were so involved. Neither of these can be considered as an effect of the dye. In the controls, the 8 sectioned hearts were as would be expected in a group of this age; there were 3 instances of slight or very slight myocardial fibrosis and nyocarditis, all on the left; one of these also showed slight left ventricular and atrial hypertrophy; an additional heart (from the animal with the peculiar bile duct proliferation) showed very slight thickening of both A-V valves. No rightsided lesions were seen.

Spleen: The spleen in rats fed 0.25% dye showed, generally speaking, slight lmyphoid atrophy together with

slight myelosis; at 0.10% dye 5 of the 6 sectioned showed slight hyperplasia, more erythroid than otherwise, while the spleen of the oldest animal was moderately atrophic, [fol. 414] with much pigment (its bone marrow was not sectioned).

Bone Marrow: The bone marrow showed very little change at 0.10%; at 0.25% moderate depletion was present in 2 of the 7 sectioned; 1 of this pair and 2 others showed a certain amount of "left shift."

Other Structures: In the controls, the 3 tumors were as mentioned under Gross Pathology, with the additional notation that the adrenal tumor was cortical in type. The enlarged and graular control kidneys showed the usual type of chronic nephritis seen in our old rats, and did not show the slight changes of another type seen in the treated rats and to be mentioned later. The pneumonias in the controls were of the usual chronic type, while those in the treated rats were more acute and of a necrotising type, with masses of bacteria. The epiphyseal lines in the leg bones of both treated groups were narrowed (markedly at 0.21%, moderately at 0.10%, showing reduced bone growth, in all probability a secondary effect through inanition rather than a direct effect of the dye. The testes in both treated groups, showed from little to much atrophy (normally, males of their ages show essentially no atrophy), and the much older controls showed from no to moderate atrophy. Because of its variability in degree, the atrophy in the treated animals is considered an indirect (inanition) effect. In each treated group, 3 kidneys showed small amounts of brown tubular epithelial pigment of the wear-and-tear type, and 3 in the 0.25% group showed slight vacuolation of the tubular epithelium; these mild changes are also considered indirect. The uteri in the 0.25% group were atrophic. Any [fol. 415] organs sectioned and not mentioned showed nothing attributable directly to the dye, no incidental changes of any consequence, and sometimes minor degrees of inanition changes.

Summary and Conclusions

Of 48 rats of both sexes started at weaning on the feeding of 0.25% of FD&C Red No. 32 (Oil Red XO) in their diet, 26 were received in the pathology laboratory after from 9

to 19 weeks of dye feeding. Similarly, of 24 rats on 0.10% of dye, 14 were received after 8 to 89 weeks (usually not over 28 weeks) of feeding. None of the treated animals was alive at this writing. Of 24 control rats, 8 are still alive, and 8 others have been received after 76 to 96 weeks on the experiment. "Received" refers to the mass of viscera, generally en bloc, fixed in 10% formalin.

On gross examination, the rats fed either level of dye showed small and pale viscera, more so at the higher level. The liver, however, was not distinctly altered in size. In both groups some livers showed slight roughness of the surface, and varying degrees of a nutmeg appearance. At the 0.25% level, the majority of the common bile ducts were enlarged in diameter, whereas at 0.10% none were. Contrariwise, the heart showed no lesions in the 0.25% animals, and only one instance of dilation in the controls, whereas almost every animal in the 0.10% group showed right-sided cardiac changes, namely one or more of ventricular hypertrophy, ventricular thrombosis, or atrial enlargement. Certain changes occurred in the controls, because of their much greater age, that did not occur in the treated animals; [fol. 416] these are given in detail in the text. Both control and treated animals showed scattered instances of pneumonia.

Microscopic examination in greater or lesser detail was done on 29 of the 48 rats received, including all 8 controls, 12 of the 14 on 0.10% dye, and 9 animals representative of those on 0.25% dye. Microscopic liver changes were much more striking than the gross appearance, particularly at the higher level of feeding. Every one of the 9 sectioned animals on 0.25% dye showed a moderate or marked degree of a process which is difficult to name precisely but which can best be called "moderate to marked subacute degeneration," whose individual factors were large irregularly shaped hepatic cells, pseudescinar formations, disorganization of the normal architecture, fibrosis, a "nibbling" type of necrosis, and several other items. In the 0.10% rats liver damage varied from very slight to moderate, and it could best be called "mild subacute degeneration and/or cirrhosis." Certain histological differences between the livers of the two groups are given. Microscopically, the hearts of the 0.25% animals showed nothing

attributable to the dye feeding, whereas in the 0.10% group the microscopic examination was simply a repetition of the gross picture, showing a constant effect of the dye feeding on the heart. Changes in various other organs were sometimes pronounced, but were for the most part attributable to inanition. In the controls, certain changes occurring principally because of advanced age are discussed; these changes were not confusing in the evaluation of changes caused by the dye.

[fol. 417] Conclusion: Feeding of 0.25% in the diet of FD&C Red No. 32 to rats caused early death, changes of inanition, and moderate to marked liver damage. Feeding of 0.10% caused less inanition, allowed somewhat longer but still short life, caused very slight to moderate liver damage, and caused one or more lesions in nearly every heart examined.

Test of FD&C Red No. 32 for Carcinogenicity by Repeated Subcutaneous Injection Into Rats

(1953)

1. First Experiment

Method: Thirty-six comparable rats (Osborne Mendel) were divided into 2 groups of 18, each group being comprised of 9 males and 9 females. The 36 rats had the following litter-mate arrangement: 4 rats (2 male, 2 female) from each of 9 litters were so divided that 1 male and 1 female from each litter-mate group was injected with either FD&C Red No. 32 suspended in glycerine or with glycerine alone.

The injections were made weekly. The FD&C Red No. 32 was suspended in 5% W/W concentration in glycerin. The control rats each received the same volume of glycerin per week as did the individual Red 32 rats. All surviving Red 32 animals received a total of 8 weekly injections as follows: 0.1 cc glycerine (containing aprox. 5 milligrams of Red 32) for each of the first 2 weeks, 0.15 cc for the 3rd week, and 0.2 cc for each of the last 5 weeks.

Results: Of the rats which received FD&C Red No. 32 one died after 7 injections, 4 died and 2 were sacrificed [fol. 418] in extermis after 8 injections. There were no fatalities among the control animals. The injections were discontinued at this time and all animals were sacrificed

a few weeks later. Toxic symptoms and findings observed in the animals which received FD&C Red No. 32 included lethargy, paleness of the animal, hemorrhage, and reduction in the size of the liver. The results of blood counts which were taken are given in Table 1 and show anemia in the experimental animals. Since the experiment had to be cut short because of toxic effects, there was no opportunity to evaluate the possible carcinogenic action of the color and a second experiment was set up.

Table 1

Blood Counts on Rats Injected With FD&C Red No. 32

	FD&C Red No. 32		Control	
5 weeks				
Hemoglobin, gm/100 ml	11.9	(5)*	15.5	(5)
Red Cells per mm³	6,100,000	(5)	8,500,000	(5)
White Cells per mm³	14,400	(5)	17,800	(5)
8 weeks				
Hemoglobin	7.9	(5)	15.5	(5)
Red Cells	4,600,000	(5)	9,800,000	(5)
White Cells	19,900	(5)	16,900	(5)
9 weeks				
Hemoglobin	11.1	(10)		
Red Cells	8,300,000	(9)		
White Cells	18,300	(9)		

* Figures in parentheses are the number of animals represented in the average shown.

[fol. 419] Second Experiment.

Method: In this experiment two groups of 18 rats, equally divided as to sex, were injected subcutaneously at weekly intervals with 0.1 cc. of a 1% (w/w) suspension of FD&C Red No. 32 in glycerin, and glycerin respectively. The rats were so distributed that one male and one female from each litter are represented in the control and the experimental group. A similar experiment on FD&C Orange No. 2 was conducted in parallel with this experiment and the same control animals served for the two colors.

Results: Because of adverse effects observed in the FD&C Orange No. 2 rats this experiment was also discontinued after 8 injections. In the case of the FD&C Red No. 32 rats there was no significant effect on growth, and no changes were observed at the injection sites.

Carcinogenicity Tests in Mice With FD&C Red No. 32

(1940)

The color was made into a glycerin paste and inserted by means of a modified trocar into the right axillary region subcutaneously of eighteen C57 black mice (10 males and 8 females]271-288) and 18 swiss white mice (18 males]21'-270). Each mouse received 10.8 milligrams of the color each injection. The first injection was made on 10-17-40 and 10-14-40 for the two groups respectively and repeated 6, 18, 23, and 35 weeks thereafter with the swiss group also receiving an injection 47 weeks after the first.

No tumors were seen at autopsy by gross examination. [fol. 420] A similar set of control mice was injected with the amount of glycerin used to make the paste at approximately the same periods.

Chronic Toxicity of FD&C Red No. 32 in Dogs

(1938-1944)

Method: In this experiment the dogs received the FD&C Red No. 32 dissolved in corn oil and administered in gelatin capsules, daily except Sunday. One male and 4 females received 5 mg. per kg. of body weight per day for 64 to 73 months. One of these females had previously received 100 mg. per kg. per day for 36 days, and 20 mg. per kg. per day for 27 days. One male dog received 100 mg. per kg. per day for about 10 months and after a month's rest received 20 mg. per kg. per day for 60 months. One of the constituents of FD&C Red No. 32, the paraisomer, was administered to 2 dogs at a dost of 5 mg. per kg. per day for 72 months. Another constituent, the meta isomer, was administered to 3 dogs at a dose of 5 mg. per kg. per day for 72 months.

Results: No adverse effects were noted during the experiment which could definitely be attributed to the color except during the period that the 2 dogs received 100 mg. per kg. per day. At this dosage there was observed moderate weight loss which was subsequently regained when this dosage was discontinued or reduced. All dogs were sacrificed at the end of 5 or 6 years on the dosage detailed under "Method."

All eleven dogs were examined grossly and microscopically. As is usual in dogs of their age, they consistently [fol. 421] showed varying numbers of splenic lymphomsteus nodules, and a few had old splenic capsular hemorrhage, another age change. The dogs had heartworms and one pneumonia. The only tumor ws an 8 mm. fibrous mass projecting from the surface of the jejunum. Two dogs had renal cysts, 5 and 8 mm. respectively. From each of these dogs microscopic sections were made of lung, heart, liver, gall bladder, spleen, pancreas, mesenteric lymph nodes, stomach (or ducdemum), small intestine, colon, kidney, adrenal, urinary bladder, testis (or ovary), prostate (or uterus), thyroid and parathyroid. All these microscopic sections showed nothing unusual except for the tumor, diagnosed as probably an argentaffinoua, and not attributable to treatment. A number of minor changes were seen in various organs; these together with the gross changes noted were considered to be within the limits of what might normally be expected in a group of dogs of this age, and it was concluded that there was no effect from treatment.

Chronic Toxicity of FD&C Red No. 32 in Dogs

(1953)

Method: This dye was fed at levels of 0.2%, 0.4%, and 0.1% in a basic diet of ground laboratory chow. Each dog was housed in an individual metabolism cage, was fed and watered daily and had free access to his food. Each dog was weighed approximately weekly. A total of 7 females and 3 males was used.

Results: The four dogs which were started at 0.2% FD&C Red No. 32 in their diet ate poorly and two were sacrificed [fol. 422] in poor condition at 26 days after having lost respectively 28% and 29% of their initial weight. The remaining two, which had lost respectively 24% and 19% were placed on a control diet for about 10 days. During this time they regained some weight and improved their physical condition. Along with two additional dogs they were placed on a diet of 0.01% FD&C Red No. 32. One of these four dogs lost about 60% of its body weight and was found dead after 173 days on the 0.01% diet. The remaining three have lost some weight but appear in fair condition after nearly 10 months on this level. All four of

the dogs on the intermediate level, 0.04%, were sacrificed in extremis at 124, 137, 148, and 148 days respectively. All had lost about 50% of their body weight. Sporadic but not severe diarrhea was observed during the experiment.

Pathological Changes in Dogs from Feeding of FD&C Red. No. 32

Path No.	Dog No.	Sex	Appr. Age, No.	% Dye in Diet	Days on Expt.	F.D.** or K.	Weight in Kg. Beg.	End
15708	D-123	F	36	0.20	26	K.	14.2	10.1
15709	105-261	M	10	0.20	26	K.	9.3	6.7
16077	M-302-a	M	15	0.04	124	K.	12.8	6.4
16120	M-302-1	F	16	0.04	137	K.	10.7	4.9
16299	98-240-a	F	63	0.04	148	K.	12.2	6.6
16300	105-262	M	12	0.04	148	K.	10.6	5.6
16376	M-277	F	53	0.01*	173*	F.D.	7.4	2.9

* After 1 month on 0.20%; weight during that month dropped from 8.8 to 6.7 kg.

** F.D. = found dead; K. = sacrificed because of poor condition.

[fol. 423] Cross Pathology

15708—Slight to moderate emaciation; very little body fat. Skin slightly dirty. Liver has slight orange-red tinge, but otherwise appears normal. Spleen pale red; bloodless. Slight-moderate yellowish radial streaking of renal cortices. No worms seen in this or any of the following dogs; cecum included.

15709—Little emaciation; some body fat. Liver slightly pale and tan. Gall bladder moderately contracted; bile dark green and gelatinous. Mesenteric and cervical lymph nodes moderately enlarged. External appearance (skin, eyes, nose, pads) plus interior of mouth normal on this and following dogs.

16077—Marked emaciation; slight dehydration. Liver slightly-moderately atrophic; firm; slightly pale and tan. Moderate amount of thick, dark bile in gall bladder. Intestinal contents normal in amount and consistency, but dark green-black in color. After fixation, stomach mucosa shows moderate number of superficial 1-2 mm. ulcerations. Bone marrow gelatinous.

16120—Marked to extreme emaciation. Tissues in general appear slightly anemic. Liver slightly atrophic; firm; dark reddish tan color. Stomach contains moderate amount

of watery coffee-ground material; mucosa appears normal. Feces brown-black. Bone marrow gelatinous (stringy), pale. Kidneys dark tan color.

16299—Moderate to marked emaciation. Liver and kidneys slightly pale and tan. Spleen shows moderate [fol. 424] amount of old capsular hemorrhage. Bone marrow slightly gelatinous.

16300—Marked to extreme emaciation. Liver slightly atrophic, pale, and tan. Gall bladder bile dark and viscid. Spleen pale red. Tissues in general slightly-moderately anemic.

16376—Extreme emaciation, slight dehydration; tissues appear anemic. Marked post mortem autolysis. Liver dark red-brown. Spleen pale red. Bone marrow slightly gelatinous.

Microscopic Pathology

Because of post mortem antelysis, microscopic examination of 16376 was limited to liver, kidney and bone marrow, including fat stains and smear respectively. From each of the remaining 6 dogs, homstoxylin sosin stained paraffin sections of formalin-fixed tissues were made from lung, heart, liver, gall bladder, spleen, pancreas, lymph nodes, kidney, adrenal, stomach (2), small intestine (3), colon, thyroid, parathyroid (except 16120), urinary bladder, voluntary muscle, testis (or ovary), uterus (or prostate, except 16300, lost), submaxillary salivary gland, and rib bone and marrow; also, from each of these 6 dogs frozen sections of liver and kidney were stained for fat with Oil Red O, a smear of bone marrow was stained with Giemsa type stain, and paraffin sections were made of liver and kidney fixed in Zenker's fluid. Some adrenals were also stained for fat and/or had portions fixed in Zenker's fluid. All of these sections were normal or essentially so except as follows.

[fol. 425] Atrophic Changes in Various Organs: This was the basic pathological pattern. For convenience, the most consistent and easily graded of these changes are shown in tabular form, and the degree of bodily emaciation is repeated. In the table, 1—slight, 2—moderate, 3—marked or severe, and 4—extreme. The changes in the bone marrow, and to a lesser extent in the spleen and lymph nodes, are a depletion of certain cells rather

than actual shrinkage in size of the organ or of its component cells, but the term atrophy is often used and generally understood, and for convenience it is used here. In the skeletal muscles, there were changes (nuclear multiplication, necrobiosis, necrosis) in addition to the atrophy, so that the total muscle lesion is a dystrophy rather than simple atrophy. Of the organs not listed, atrophic changes in the ovary and uterus were the most common.

The figures in the table have no mathematical exactness for comparative purposes because of subjective factors, differences in the atrophic process among various organs, and the difference between depletion and atrophy mentioned above. Because of the great liability of the bone marrow, a few words of explanation about it may help. Our dog rib marrow, on the average, normally are made up of (by inspection, not measurement) about 1/3 hematopoietic (plus a small percentage of stroma) cells, about 1/2 fat cells, and the remainder by, chiefly, capillary blood vessels. In determining these values the artefacts of shrinkage spaces, and the relative unobtrusiveness of fat cells in routine paraffin sections have been considered. The moderate bone marrow depletion shown in the table means a reduction in hematopoietic cells of around 50% of the normal.

[fol. 426]

Pathology No.	Bodily Emaciation	Degree of Atrophic Changes						
		Liver	Spl.	Lym.N.	Mar.	Tes.	Pro.	Muscle
15708	1-2	±	0	0	0	Fem.	Fem.	0
15709	1	0	0	0	0	1-2	2	1
16077	3	3	2	1	2	2	2	1
16120	3-4	2-3	2	2	2	Fem.	Fem.	2-3
16299	2-3	1	1	1-2	2	Fem.	Fem.	±
16300	3-4	2	2	1-2	2	3	Lost	2
16376	4	2-3	N.S.	N.S.	±	Fem.	Fem.	N.S.

Abreviations in last 6 columns mean respectively, Spleen, Lymph Nodes, Marrow, Testis, Prostate, Female, and Not Sectioned.

Changes Other than Atrophy and/or Cellular Depletion: Fatty change in the liver was slight. Some times our supposedly normal dogs show a very small amount of stainable liver fat. Five of the present lot showed a very small amount, 15709 showed a slight degree of fatty change, and 16376 (the animal found dead) a slight to moderate degree. In the kidney, normally present fat

(in other laboratories as well as our own) has a wider variation in amount, and the present group of dogs was not outside this normal range of variation. In the stomach, 16120 and 16299 showed slight ballooning (enlargement and rarefaction) of the fundic parietal cells; 16077 showed small foci of recent mucosal necrosis. In the bone marrow, the myeloid/erythroid ratio was determined only by inspection, not counting. In the first dog in the table it appeared slightly increased; in the remainder it was not definitely abnormal, although the gelatinous nature of the majority of the marrows interfered with obtaining [fol. 427] well-stained smears. Hemosidarin in the bone marrow and liver varied from none to moderate in amount; the animals showing the most of this pigment were 16299 and 16376. Certain changes in the skeletal muscles were previously mentioned; both these and the atrophy were greater in the thigh than in the neck, the 2 muscle sites routinely sectioned. Frank necrosis was not prominent, but nuclear multiplication and necrobiosis more or less paralleled the atrophy.

Except for the single bone marrow, the positive findings mentioned in the above paragraph can be attributed to treatment, as, of course, are the atrophiec previously mentioned. Certain other changes, scattered among the various organs and none of major proportions, cannot be attributed to treatment.

Summary and Conclusions

Cross and microscopic pathological examination has been made of 7 dogs fed FD&C Red No. 32 (Oil Red XO) at dosage levels of from 0.01% to 0.20% of the diet for periods of 26 to about 200 days. One dog was found dead and the others sacrificed because of their poor condition.

On gross examination, the only external change of significance was consistent emaciation, usually pronounced and varying from slight to extreme. Internally, the common changes were slight or moderate pallor (anemia) of the organs and tissues in general, gelatinous bone marrow, and atrophy of the liver. No worms were found.

[fol. 428] Detailed microscopic examination was done on 6 of the 7 dogs, and some on the remaining one. The microscopic picture was consistent, the basic pattern being

that of atrophy and/or cellular depletion in various organs, the most frequently affected being liver, spleen, lymph nodes, bone marrow, genital organs, and skeletal muscle. In general, these atrophies paralleled the degree of emaciation. In addition, the changes attributable to treatment included slight fatty change in the liver; slight changes in some stomach, dystrophic changes in skeletal muscle in addition to the atrophy, and a certain amount of hemosiderosis of liver and bone marrow. The changes were greater in those animals fed the low doses for longer periods than in those fed the high dose for shorter periods.

Cathartic Action of FD&C Red No. 32 in Dogs (1952)

Ten of the eleven dogs which had been found to be sensitive to the cathartic action of FD&C Orange No. 1 were tested on FD&C Red No. 32. The dogs were fasted overnight, given a weighed amount of the color in a capsule and then fed two hours later. Of the ten dogs which received a dose of 200 mg. each, eight developed diarrhea. When five of the dogs were later similarly tested at a dose of 100 mg. each, four developed diarrhea and one gave questionable results.

[fol. 429] EXHIBIT 8.

Table 9. A Summary Table on the Concentration of Dye on Color-Added Oranges and in Products Made from Color-Added Oranges.

Substance	Concentration of dye in ppm
Whole fruit (extraction and chromatographic separation)	3.39— 4.69
Whole fruit (chloroform washing)	4.96— 6.78
Peel of fresh fruit (extraction and chromatographic separation)	17.63—24.39
Peel of fresh fruit (chloroform washing)	25.79—34.26
Juice	.04— .07
Candied peel	7.4
Marmalade	1.8

[fols. 429 a-b] Clerk's Certificate to foregoing transcript omitted in printing.

[fols. 430-431] IN SUPREME COURT OF THE UNITED STATES,
OCTOBER TERM, 1957

No. —

[Title omitted]

ORDER EXTENDING TIME TO FILE PETITION FOR WRIT OF CERTIORARI—November 27, 1957

Upon consideration of the application of counsel for petitioner(s),

It is ordered that the time for filing petition for writ of certiorari in the above-entitled cause be, and the same is hereby, extended to and including January 3d, 1958.

Hugo L. Black, Associate Justice of the Supreme Court of the United States.

Dated this 27th day of November 1957.

[fol. 432] IN SUPREME COURT OF THE UNITED STATES,
OCTOBER TERM, 1957

No. 703

MARION B. FOLSOM, Secretary of Health, Education and Welfare, Petitioner,

vs.

FLORIDA CITRUS EXCHANGE, FRANK R. SCHELL, et al.

ORDER ALLOWING CERTIORARI—March 17, 1958

The petition herein for a writ of certiorari to the United States Circuit Court of Appeals for the Fifth Circuit is granted.

And it is further ordered that the duly certified copy of the transcript of the proceedings below which accompanied the petition shall be treated as though filed in response to such writ.

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JOHN F. DAVIS, CLERK

In the Supreme Court of the United States

OCTOBER TERM, 1961

MARION B. FOLSOM, SECRETARY OF HEALTH, EDUCATION AND WELFARE, PETITIONER

v.

FLORIDA CITRUS EXCHANGE, ETHEL E. SOSNIK, ET AL.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

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In the Supreme Court of the United States

OCTOBER TERM, 1957

No.—

MARION B. FOLSOM, SECRETARY OF HEALTH, EDUCATION AND WELFARE, PETITIONER

v.

FLORIDA CITRUS EXCHANGE, FRANK R. SCHELL, ET AL.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

The Solicitor General, on behalf of Marion B. Folsom, Secretary of Health, Education, and Welfare, prays that a writ of certiorari issue to review the judgment of the United States Court of Appeals for the Fifth Circuit, entered in the above cases on July 12, 1957.

OPINIONS BELOW

The Secretary's order (R. 281) appears in 20 F. R. 8493. The opinions in the Court of Appeals, printed in the Appendix, *infra*, pp. 25–52, are reported in 246 F. 2d 850.

JURISDICTION

The judgments of the Court of Appeals were entered on July 12, 1957 (Appendix, *infra*, pp. 52–53). A motion for rehearing before the court *en banc* was denied on August 28, 1957, Chief Judge Hutcheson

dissenting (Appendix, *infra*, p. 54). On November 27, 1957, by order of Justice Black, the time for filing a petition for a writ of certiorari was extended to and including January 3, 1958. The jurisdiction of this Court is invoked under 28 U. S. C. 1254 (1) and 21 U. S. C. 371 (f) (4).

QUESTIONS PRESENTED

1. Whether the court below erred in directing the Secretary of Health, Education, and Welfare to certify as harmless for use in the coloring of oranges a coal-tar color which admittedly has been properly found to be poisonous and properly decertified for general use under Section 406 (b) of the Federal Food, Drug, and Cosmetic Act.

2. Whether the provisions of Section 406 (a) authorizing the Secretary to establish tolerances for use of deleterious substances in food, when required in production, applies to coal-tar colors found not to be harmless under Section 406 (b).

3. Whether "required in the production," as used in Section 406 (a), means required in post-harvest treatment of oranges for greater eye-appeal in the market place.

4. Whether, assuming that the Secretary has power to establish tolerances for use of poisonous coal-tar color in oranges, it was proper for the Court of Appeals to assume that *prima facie* the coloring for oranges was required for production, and not dangerous in the particular use, and to cast the burden on the Secretary to show that such use was dangerous.

STATUTE INVOLVED

The Federal Food, Drug, and Cosmetic Act, as amended, 52 Stat. 1040, 70 Stat. 512 (21 U. S. C. 301, *et seq.*), provides in pertinent part as follows:

SEC. 402. A food shall be deemed to be adulterated—

(a) (1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health; or (2) if it bears or contains any added poisonous or added deleterious substance which is unsafe within the meaning of section 406; * * *

(c) If it bears or contains a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by section 406 * * * *Provided further,* That this paragraph shall not apply to oranges meeting minimum maturity standards established by or under the laws of the States in which the oranges were grown and not intended for processing (other than oranges designated by the trade as "packing house elimination") the skins of which have been colored at any time prior to March 1, 1959, with the coal-tar color certified prior to the enactment of this proviso as FD&C Red 32, or certified after such enactment as External D&C Red 14 in accordance with section 21, Code of Federal Regulations, part 9: *And provided further,* That the preceding proviso shall have no further effect if prior to

March 1, 1959, another coal-tar color suitable for coloring oranges is listed under section 406." [21 U. S. C. 342].

* * * * *

SEC. 406 (a) Any poisonous or deleterious substance added to any food, except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice shall be deemed to be unsafe for purposes of the application of clause (2) of section 402 (a); but when such substance is so required or cannot be so avoided, the Secretary shall promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health, and any quantity exceeding the limits so fixed shall also be deemed to be unsafe for purposes of the application of clause (2) of section 402 (a). * * * In determining the quantity of such added substance to be tolerated in or on different articles of food the Secretary shall take into account the extent to which the use of such substance is required or cannot be avoided in the production of each such article, and the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances.

(b) The Secretary shall promulgate regulations providing for the listing of coal-tar colors which are harmless and suitable for use in food and for the certification of batches of such colors, with or without harmless diluents [21 U. S. C. 346].

* * * * *

SEC. 701 (f) (1). In a case of actual controversy as to the validity of any order under sub-

section (e), any person who will be adversely affected by such order if placed in effect may at any time prior to the nineteenth day after such order is issued file a petition with the Circuit Court of Appeals of the United States for the circuit wherein such person resides or has his principal place of business, for a judicial review of such order * * *.

* * * * *

(3) The court shall have jurisdiction to affirm the order, or to set it aside in whole or in part, temporarily or permanently. * * * The findings of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive.

(4) The judgment of the court affirming or setting aside, in whole or in part, any such order of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari * * *" [21 U. S. C. 371].

STATEMENT

The Secretary of Health, Education, and Welfare, after public proceedings and on the basis of uncontroverted evidence, issued a final order on November 10, 1955, removing coal-tar colors FD&C Orange No. 1, Orange No. 2, and Red No. 32 from the approved list of harmless colors for unrestricted use in food, drugs, and cosmetics (R. 281). This order was reviewed generally and upheld by the Second Circuit (*Certified Color Industry Committee* v. *Secretary of Health, Education and Welfare*, 236 F. 2d 866), and was reviewed and held invalid, insofar as it concerns Red. No. 32 as used for coloring oranges in Texas and

Florida, by the court below in this case. The pertinent facts are as follows:

1. Red 32 had been placed on the approved list in 1939, after a public hearing at which its harmlessness was apparently established. New investigations by the Department of Health, Education, and Welfare were initiated after scientific questions as to the possible carcinogenicity of Red 32 and other coal-tar colors were raised. These investigations were spurred by the Hearings before a Select Committee of the House of Representatives to Investigate the use of Chemicals in Food Products.[1] The investigations, conducted with small laboratory animals (rats and dogs), were begun in 1951 and completed in 1953 (J. A. 54–55, 58–65, 68–84, 86–93). The result established that the three colors involved in the instant order (Red 32, Orange 1, and Orange 2) had significant toxicity.

Upon completion of the investigations, the results were given to the certified color industry (J. A. 46), and the Department announced that a hearing would be held with a view to removing Red 32 from the list of harmless colors. At the hearing, the sole scientific witness for the color industry stated that the industry had no pharmacological data of its own to present, that the industry had done no such work since 1939, and that it was "willing to accept the result of stud-

[1] See the opinion below, Appendix, *infra*, p. 29; *Certified Color Industry Committee* v. *Secretary*, 236 F. 2d 866, 867 (C. A. 2); Hearings, Select Committee, 81st Cong., 2d Sess. (pursuant to H. Res. 323), pp. 220, 238; 82d Cong., 1st Sess. (pursuant to H. Res. 74), part 1, pp. 325, 326, 332, 334; 2d Sess. (pursuant to H. Res. 74 and 447), part 3, pp. 1353–1355, 1360, 1363, 1369, 1381.

ies made by the Food and Drug Administration" (J. A. 46–49). The Florida Citrus Commission also indicated that it did not oppose "any action which the Secretary may deem advisable on the basis of the record" (J. A. 43–44).

In his order of November 10, 1955, the Secretary found that the three colors, including Red 32, are toxic, *i. e.*, poisonous, and forbade their use on foods.

2. The court below found that the evidence justified the finding that Red 32 was toxic (Appendix, *infra*, p. 41). The detailed findings reveal that Red 32 is the most toxic of the three colors. Pharmacological studies established that at 0.5% and 0.25% in the diet of test rats (5,000 to 2,500 parts per million) the color killed most of the rats in a short time. 0.1% (1,000 ppm) had the same, but a less rapid, effect. On autopsy, the animals had liver damage, anemia, and enlargement of the right side of the heart.[2] In dogs, 0.04% (400 ppm) caused deterioration, weight loss, sporadic diarrhea, moderate atrophy of vital organs and muscular dystrophic changes. One dog at 0.01% (100 ppm), the lowest test dosage fed, lost weight and died. A single oral dose of 100 milligrams (about ⅓ the weight of an ordinary 5 grain aspirin tablet) produced diarrhea (R. 282, Findings 7–8).

The Secretary found the evidence inadequate to support findings as to the amounts of color likely to

[2] No heart damage was found in rats fed 0.25% (2,500 ppm); yet at 0.1% (1,000 ppm) heart damage was definitely shown. The pathologist remarked on the fact of the lower dosage "showing a constant effect of the dye feeding on the heart" (J. A. 80, 81).

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be ingested by man from his food, drugs, and cosmetics (R. 282, Finding 10). The industry committee representative testified that his company (one of the largest in the business) had done no work to learn how much of these colors is found on various foods (J. A. 49). The Secretary concluded that, in any event, he had no statutory authority under Section 406 (b) of the Federal Food, Drug, and Cosmetic Act to list colors of established toxicity and then attempt by regulation to restrict the levels of use of the poisonous colors in selected foods, drugs, and cosmetics as a means of protecting the public from the consumption of harmful amounts of the toxic colors (R. 282, Conclusions 1–4).

3. Petitions asking the Secretary to reopen the hearing were made by the Certified Color Industry Committee (R. 259), Eli Lilly & Co. (R. 268), and Frank R. Schell (R. 209). Their purpose was to offer evidence to establish that the amounts of the three colors normally used in a variety of foods and drugs, and more particularly to establish that the amounts of Red 32 used in coloring oranges, were far below the amounts shown toxic to test animals (R. 212). The aim was to show that the amounts of color normally used are wholly insignificant from a toxicological standpoint, and at least that safe tolerances could be established for the three colors in a number of foods and drugs.

The Secretary refused to reopen (R. 211, 262–267, 277–280). His reasons were that the animal data failed to establish a safe level of dosage for the test animals; that man is more susceptible than the test animals, making it impossible to transpose the animal

data directly to man; and that Red 32 had been involved in a recent food poisoning episode, establishing the possiblity that dangerous amounts would be used. The Secretary found the normal use data submitted in the petitions to reopen to be inaccurate and incomplete, the pharmacological testing inadequate to establish the extent of toxicity to a certainty that would permit him to fix safe tolerances, and that there was no statutory authority on which he could issue regulations establishing tolerances for toxic coal-tar colors.

4. The Certified Color Industry Committee sought judicial review in the Court of Appeals for the February 8, 1956 (R. 47, 48). After consolidation, the Second Circuit. On August 10, 1956, that Court of Appeals affirmed the order, 236 F. 2d 866. Eli Lilly thereupon dismissed its petition for judicial review in the Seventh Circuit (C. A. 7, No. 11,682).

The present cases were filed in the Fifth Circuit on February 8, 1956 (R. 47, 48). After consolidation, the printed record was filed in February 1957. The cases were argued in May 1957, and on July 12, 1957, the Court of Appeals entered its judgment setting the order aside insofar as it removed Red 32 from the approved list of coal-tar colors that might be used on Texas and Florida oranges. The final judgment required the Secretary to certify henceforth sufficient batches of this color as may be necessary for Texas and Florida oranges. But the court provided that nothing in its judgment should restrict the Secretary from making further investigations and conducting hearings to determine whether Red 32 is required in the production of oranges and to determine the tolerances, if any, that are safe and harmless. Under

the judgment, Red 32 will have to be retained on the approved list and certified by the Secretary as harmless for coloring oranges "until there is evidence that in the amounts used, and in the manner of use, oranges colored with Red 32 are unsafe for human consumption."

5. Before the administrative process had been completed, steps were taken in the Congress to enact legislation to keep Red 32 on the approved list for coloring oranges. After the tentative order issued (R. 52–54), a bill was introduced into the 84th Congress, H. R. 7732, to require the Secretary to continue the certification of Red 32 for coloring oranges until a color that is "more acceptable" (less toxic) should be "listed and made available for use." Hearings were held before the House Committee on Interstate and Foreign Commerce on February 10, 1956, a few days after the present cases were filed in the Court of Appeals for the Fifth Circuit. The Department of Health, Education and Welfare opposed the bill. It proposed a temporary compromise to continue Red 32 on the list for coloring certain oranges for a period of not to exceed 3 years. This, it explained, was to allow time "for the development of a color that is not toxic," "for further exploration of the toxicity of FD&C Red 32," and "for further congressional consideration if a new color should not be found, and if it should be necessary to amend the law to authorize the Department to prescribe a tolerance for Red 32 on oranges and impose other conditions to safeguard public health." In doing this, the Department explained that it had no positive proof that this temporary use would

involve a likelihood of injury, but neither was there evidence available to establish that this use was wholly safe. On the other hand, the Department said that it could not agree to H. R. 7732, which would require the indefinite listing of Red 32 for oranges "before its safety for the purpose has been finally established" (Hearings, House Committee on Interstate and Foreign Commerce on H. R. 7732, 84th Cong., 2d Sess., pp. 2–3).

Both the House and Senate Committees adopted the Department's recommendations, and both made it clear that this temporary legislation was not intended to affect the outcome of the judicial review proceedings then under way in New York, Chicago, and New Orleans. H. Rep. 1982, 84th Cong., 2d Sess., p. 3, and S. Rep. 2391, 84th Cong., 2d Sess., pp. 2–3.

The result of this Congressional consideration was Public Law 672, 84th Cong., 2d Sess., enacted July 9, 1956, under which the Florida and Texas orange growers were exempted from the prohibitions against Red 32 (now External D and C Red No. 14) until March 1, 1959.[8]

[8] Public Law 672 reads as follows:

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That paragraph (c) of section 402 of the Federal Food, Drug, and Cosmetic Act, as amended, is amended by inserting immediately before the period at the end thereof a colon and the following: "*Provided further*, That this paragraph shall not apply to oranges meeting minimum maturity standards established by or under the laws of the States in which the oranges were grown and not intended for processing (other than oranges designated by the trade as 'packing house elimination'), the skins of which have

Section 406 (b) of the Federal Food, Drug, and Cosmetic Act directs the Secretary of Health, Education, and Welfare to promulgate regulations providing for the listing of coal-tar colors which are harmless and suitable for use in food. Under that provision, the Secretary has, in the order under review, barred Red 32 and two orange colors. The order flatly prevents use of these colors, for Section 402 (c) defines a food as adulterated if it "bears or contains a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by section 406". Until March 1, 1959, there is the temporary statutory exception from Section 402 (c)—noted in the Statement, *supra*, p. 11—granted by P. L. 672 to Red 32 used for coloring oranges. But in invalidating the Secretary's order, the court below has, in effect, read into Section 402 (c) a permanent exception which not only will apply to coloring for oranges beyond March 1959, but which will permit possible exceptions in other fields as well. The court has held that there must be inserted into Sections 402 (c) and 406 (b) (dealing specifically with coal-tar colors) the provisions of Section 406 (a) which declares that the Secretary may permit the adding of a poisonous or

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been colored at any time prior to March 1, 1959, with the coal-tar color certified prior to the enactment of this proviso as F. D. & C. Red 32, or certified after such enactment as External D. & C. Red 14 in accordance with section 21, Code of Federal Regulations, part 9: *And provided further*, That the preceding proviso shall have no further effect if prior to March 1, 1959, another coal-tar color suitable for coloring oranges is listed under section 406".

deleterious substance to food "where such substance is required in the production thereof or cannot be avoided by good manufacturing practice," under regulations limiting the quantity which the Secretary finds necessary for the protection of public health. Then the court goes still further to construe "required in the production thereof," as used in Section 406 (a), as meaning required for marketing by a "substantial segment" of the orange-producing industry. Finally, the court decides (Appendix, *infra*, p. 46) that the use of coal-tar coloring for oranges should be continued, irrespective of the date fixed by Congress, and regardless of any proof by respondents that a safe tolerance can be fixed, until the Secretary is prepared to show that "in the amounts used, and in the manner of use, oranges colored with Red 32 are unsafe for human consumption."

We believe that this erroneous decision warrants review and correction by this Court. Its reasoning and result conflict with that of the Second Circuit in *Certified Color Industry Committee* v. *Secretary of Health, Education and Welfare*, 236 F. 2d 866. It effectively defeats the object of Congress—in passing P. L. 672, the temporary legislation—of stimulating the color industry to develop new and safer coloring. And the decision sets up requirements for the certification of coal-tar colors which have significant and immediate impact, not only beyond the period fixed by Congress for oranges, but for other coal-tar colors used on other foods, *e. g.*, yellow colors used principally in margarine. For these reasons it is important that the ruling below be reviewed at this time.

I

A. There is a basic conflict between the decision below and that of the Second Circuit in the *Certified Color* case. It is true, as the majority opinion below points out, that *Certified Color* involved the question of the use of Red 32 generally, whereas this holding concerns only Red 32 as applied to coloring for oranges. But the fact is that the Second Circuit's judgment precludes certification of Red 32 to manufacturers while the present judgment requires the Secretary to issue certificates of harmlessness of Red 32 to the same manufacturers so long as they say they intend to sell the color to Texas and Florida orange growers.

There is also a direct conflict in reasoning. The Second Circuit held that, even if the Secretary had power to fix tolerances for coal-tar colors (a question it did not decide), the court could not, on the record before it, require the Secretary to do so. It pointed out that there was nothing in the record to indicate how much of the coal-tar colors a human being could ingest over a period of years without harmful effects, and that it might not be possible to demonstrate the precise cumulative effect, over 20 to 30 years of consumption, of specified amounts of color. On the other hand, the court below, on the same record, made a determination that coloring for oranges is safe, merely on the basis of the Secretary's statement that coloring for oranges has not been proved to be harmful, and without considering what effect there might be if other industries could show

a similar need for harmful coloring. In contrast to the Second Circuit, the ruling below does require the Secretary to establish tolerances unless he affirmatively proves that the court's assumption as to the safety of Red 32 is wrong. In short, the court below has given its stamp of approval to an acknowledged poison and cast the burden on the Secretary to show that the coloring is not safe for oranges. The Second Circuit has held that the Secretary has no such burden.

B. There is a present need for resolution of this conflict of circuits, even though the temporary statute suspends the operation of the Secretary's order, as to Red 32 for oranges, for another year. Congress intended by P. L. 672 to press the color industry and the orange growers into prompt development of a harmless color or at least into scientific research which might provide a sound factual basis for a safe tolerance for Red 32 on oranges. See the terms of P. L. 672, fn. 3, *supra*, pp. 11–12.[4] The Second Circuit

[4] The temporary legislation did not revoke the Secretary's order nor modify its terms. What it did was to excuse the Texas and Florida orange growers from adulterations that would otherwise arise prior to March 1, 1959, from the use of Red 32 (now External D&C Red No. 14). Though the order remains in effect under the statute, insofar as it removed Red 32 from the "harmless" list a statutory exception to the adulteration defined in Section 402 (c)—the use of uncertified coal-tar colors on foods—was made so that it may not be applied prior to March 1, 1959, against the Texas and Florida growers who use Red 32 under the conditions specified in the exception. Fourteen months from now the exception expires by its own terms, and any oranges colored with Red 32 would thereupon be deemed adulterated.

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has also left the burden where it belongs, on the industry either to prove that the color is safe or to discover a safe new product.

The decision below means, however, that the industry and the growers can rest on the Fifth Circuit's judgment and do nothing—that it is the Department which must develop the facts to show a positive danger to health before it can preclude the use of a color it has proved to be generally poisonous. There is now no reason for the industry to institute studies or to take action. On the other hand, the scientific evidence to support the course of action required of the Secretary by the court below does not now exist, and the investigations to obtain it will involve considerable expense and require at least two years after the study is commenced. If the Secretary really does have the burden which the decision below casts upon him, he should know that now. If, as we think, the burden is properly on the industry, the decision below, under which the industry need do nothing, should not be allowed to stand.

Moreover, the decision below has a direct and immediate impact upon other colors and other proceedings. For example, on May 4, 1957, the Department published an order removing certain yellow colors, used principally in margarine, from the list of colors available for unrestricted use in food, drugs, and cosmetics. The reasoning applied by the court below to Red 32 may well be urged in relation to oleomargarine. The Secretary should know whether, in the promulgation of this order, he must be guided by the decision of the Second Circuit or by the ruling

of the court below. Coloring is probably as important a factor in the marketing of margarine as it is in the distribution of oranges.[8] The Fifth Circuit's decision thus has an immediate practical effect, both with respect to coloring for oranges and in its wider implications for the Secretary's color proceedings in general.

C. Nor have the issues become moot in the technical sense because the temporary legislation postpones the effectiveness of the order with respect to oranges. Review of the Secretary's regulations is authorized by the Federal Food, Drug, and Cosmetic Act, and must be sought within 90 days after the final rules are announced. Any person who will be adversely affected if the order is placed in effect is given standing to challenge the rules. Since this involves judicial review of administrative rule-making, it is always the future effect of the regulations rather than their past application which makes the case justiciable. In *Federal Security Administrator* v. *Quaker Oats Company*, 318 U. S. 218, the regulations were issued May 26, 1941, to be effective January 1, 1942. Review proceedings were begun on August 22, 1941.[9]

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[8] In addition to the basic holding below that the Secretary must establish tolerances, there is the additional ruling that he must consider sales appeal as a factor in determining whether a toxic color is "required in the production" of food. Both questions would be important in passing (under the rules laid down below) on the suitability of certain yellow colorings for margarine.

[9] The requirement that riboflavin be an ingredient of enriched farina was not to become effective until April 1943, because that vitamin was in short supply. 318 U. S. 223, fn. 3.

It is not at all unusual for an executive agency to place an effective date on its rules which will allow the affected industry time to adjust to the new requirements.' But a postponed effective date does not destroy the right to judicial review. Review can be obtained only within 90 days after promulgation of the rules, though they may not become effective by their own terms for a year or more. In this case, the fact that Congress, rather than the executive agency, gave the citrus growers additional time to adjust to the new rules does not preclude or frustrate the statutorily-permitted judicial review.

In *Reade* v. *Ewing*, 205 F. 2d 630, the Court of Appeals for the Second Circuit held that a consumer had standing to obtain review when he alleged that the Secretary had erroneously permitted synthetic vitamin A in the standard for oleomargarine, and that the petitioner's health might be adversely affected if the ingredient was, as he alleged it to be, of uncertain safety. The consumer was characterized as a private attorney general to bring suit to restrain wrongdoing public officials. His interest was much more remote than that of the Texas and Florida orange growers, for so long as the Secretary's order stands they must immediately take action to develop a harmless substitute color or to study the toxic potential of Red 32, and the oranges containing it, to provide the evidence on which a safe tolerance

'Only recently the Department issued new rules respecting the label statements that must be made concerning the niacin and riboflavin content of foods for special dietary use. The effective date of the rules was set for July 1, 1958, to permit the necessary revision of existing labels. 22 F. R. 4910.

may be established. Since such studies require at least two years, it is obvious that the order immediately affects them even though it may not be applied to condemn their oranges before March 1, 1959.[8]

II

Not only are the rulings of the court below of decided current and future importance; they are also demonstrably incorrect.

A. The court first erred in holding that the provisions of Section 406 (a) (enabling the Secretary to fix tolerances for deleterious substances required in production) operate as an exception to Section 402 (c), providing that a food is adulterated if it bears a coal-tar color other than one which has been certified as harmless under Section 406 (b). Coal tar colors have always been recognized as having potentialities of danger. See Calvery, *Coal-Tar Colors, The American Journal of Pharmacy*, Vol. 114, No. 9; Statement of Walter G. Campbell, on S. 1944, 73d Cong., 2d Sess., Dunn, *Legislative History, Federal Food, Drug, and Cosmetic Act* (1938), p. 1066. In the very same Section 406 in which Congress provided in subdivision (a) for tolerances when required, it enacted subdivision (b) providing for the certification only of harmless coal-tar colors. This special singling out of coal-tar colors shows that Congress considered them a special problem. In all the Congressional dis-

[8] This Court's decisions in *Columbia Broadcasting System* v. *United States*, 316 U. S. 407; *United States* v. *Storer Broadcasting Co.*, 351 U. S. 192, and *Pierce* v. *Society of Sisters*, 268 U. S. 510, also support our view that the case is still ripe for consideration.

cussion of Section 406, paragraphs (a) and (b) were discussed separately and there was no suggestion anywhere that a tolerance for a poisonous coal-tar color could or should be established under paragraph (b).

The legislative history of 406 (b) likewise shows that Congress intended the Secretary to list "those colors which were demonstrated to be without adverse physiological action, and which from a technical standpoint were suitable for use as food colors." S. Rep. 361, 74th Cong., 1st Sess., pp. 6–8 (1935); Dunn, *Legislative History, Federal Food, Drug, and Cosmetic Act,* (1938), p. 243. Congress intended to correct a weakness of the original 1906 Pure Food and Drugs law under which "[n]o action [could] be taken unless it [could] be proved that colors or their impurities are poisonous *and that they are present in such quantities as may be harmful to health"* (emphasis added). Senator Copeland's memorandum on S. 1944, 73d Cong., Dunn, *op. cit.,* pp. 30–31. The new law was designed to prevent the use of poisonous coal-tar colors without the necessity of proof that the poison was "present in such quantities" in a particular food to render that food "injurious to health." *Wood Manufacturing Co.* v. *United States,* 286 Fed. 84 (C. A. 7), is the case Congress intended to overturn.

The purpose of Section 406 (b) was to require the Department to list and certify only innocuous coal-tar colors, which could then be used by all food, drug, and cosmetic manufacturers, without restraint as to quantity or commodity, in order to achieve any desired tinctorial hue in or on any number of commodities. There was no idea of authorizing the use of

poisonous colors on a single food, even within the limits of stringent tolerances; the danger of cumulation of the poison, over a period of years, was believed too great to permit such necessarily-inaccurate tolerances. And the whole question of safe tolerances becomes much different if more than one product is involved. Assuming that the amount of coloring used for oranges alone would be safe, and in itself the amount of coloring used for margarine would be safe, there would still remain the question of whether the amount of coloring used in both margarine and oranges would be harmless. And since there may be other industries which would make out a similar case for toxic coloring, the question of safe tolerances becomes even more complicated and hazardous to assay.

B. Even assuming that coal-tar colors could come within the scope of the "tolerances" provision of Section 406 (a), the Fifth Circuit has misinterpreted that section in holding that "required in the production" means "required in the production *for market*" by a particular industry (Appendix *infra*, pp. 41–43, emphasis added).

By Section 406 (a), Congress established a strict rule of exclusion against all poisonous and deleterious substances which might be added to our foods. This was without regard to whether the added substances might or might not render the treated food injurious to health. It was enough that the added substance itself was a poisonous or deleterious one. A single exception was made. When the added substance was required in the production of food or could not be avoided by good manufacturing practice, the Secretary was authorized to establish a tolerance for it,

taking into account the extent to which the added substance was required or was unavoidable, the amount of the poison that might be safely tolerated, the extent of requirement or unavoidability of the poison on other foods, and the other ways in which the consumer might be affected by the same or other poisonous or deleterious substances.

This was a new legislative approach to added poisons. Under the Pure Food and Drugs Act of 1906, Section 7, 34 Stat. 768, 770, food was declared adulterated if it contained and added poisonous or deleterious ingredient "which may render such article injurious to health." This Court, in *United States* v. *Lexington Mill & Elevator Co.*, 232 U. S. 399, 409–411, held that under the 1906 language a food was adulterated if it contained any added poisonous or deleterious ingredient which may possibly injure the health of any consumer, "the strong and the weak, the old and the young, the well and the sick." If the added substance in the food could not "by any possibility" injure the health of any consumer, the small addition of poisonous or deleterious ingredients was not condemned. As strong as this prohibition was, it did not go far enough. Each food had to be considered alone, and there was no adulteration unless the particular food contained enough poison so that that food "may" be injurious to health. Small amounts of the same poison in a variety of common foods in the diet were beyond effective control.

The new provision in Section 406 (a) of the Federal Food, Drug, and Cosmetic Act was designed to arm the Department with power to establish tolerances for the entire variety of foods in which a

common poison or related poisons were required or were unavoidable, and thereby to limit the total intake of each such poison to a safe level. See testimony of Walter G. Campbell, Chief, Food and Drug Administration, before the House Committee on Interstate and Foreign Commerce, on S. 5, 74th Cong., Dunn, *op. cit.*, pp. 1250–1251; H. R. Rep. 2139, 75th Cong., 3d Sess., p. 6, Dunn, *op. cit.*, p. 820.

Considering the very narrow scope of this exception created by Congress, it is inconsistent with its purpose to construe "required in the production" to cover post-harvest treatment of fruit, after it has been produced, for the sole purpose of making it look more attractive and therefore more readily salable. This interpretation of Section 406 (a) as justifying use of poisons when required for *marketability* opens up all sorts of possibilities beyond coloring as such. If marketability rather than actual production is to be the test of necessity, it is evident that the amount of poison in the American diet can be greatly increased.

C. Even assuming the correctness of the statutory interpretations by the court below, it erred in itself making the requisite finding that coloring of oranges was required for production (including marketing) and casting the burden on the Secretary to show that safe tolerances cannot be established. As we have noted, tolerances safe for oranges alone might not be safe if, under the interpretation of the court below, other products can also show that they should be allowed to use coal-tar colors because required in their "production" or marketing. The fact that Congress created (in P. L. 672) a deferment for one particular

product, on a finding that the amount of coloring used in that product for a short period would not endanger public health, does not justify a court in making the judgment on its own, on a theory of the statute which would also apply to other products and for an indefinite period. And certainly the burden of showing danger from an admitted poison should not rest on the Secretary. Even on the court's own view, it should have remanded the case for further proceedings without setting aside the order.

CONCLUSION

For the foregoing reasons, we believe that this petition for a writ of certiorari should be granted and the case determined on its merits at this time. However, should the Court be of the view that no decision should be reached on the important questions discussed above until after March 1, 1959, when P. L. 672 expires, we urge that certiorari be granted, the judgment of the Court of Appeals vacated, and the case returned to it for disposition after the temporary legislation ends.

Respectfully submitted,

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JANUARY 1958.

APPENDIX

In the United States Court of Appeals for the Fifth Circuit

No. 15934

FLORIDA CITRUS EXCHANGE, ET AL., APPELLANTS

v.

M. B. FOLSOM, SECRETARY OF THE DEPARTMENT OF HEALTH, EDUCATION AND WELFARE, APPELLEE

No. 15948

FRANK R. SCHELL, APPELLANT

v.

M. B. FOLSOM, SECRETARY OF THE DEPARTMENT OF HEALTH, EDUCATION AND WELFARE, APPELLEE

ON PETITIONS FOR REVIEW OF AN ORDER OF THE SECRETARY OF HEALTH, EDUCATION AND WELFARE

(July 12, 1957)

Before HUTCHESON, Chief Judge, and JONES and BROWN, Circuit Judges.

JONES, Circuit Judge: In the nineteen-thirties growers and packers of oranges in Florida and Texas began the practice of adding color to the rind of oranges. Early oranges, maturing during warm

weather, will ripen to full maturity with the skin still green in color. Oranges maturing in the late winter or spring may fully ripen and undergo a "regreening" of the rind. The orange-purchasing public requires an orange-colored orange and will not accept those with green rinds. Representatives of a substantial number of those engaged in the growing and marketing of citrus fruits in the two states assert that severe economic reverses would result from a prohibition of adding color to the fruit; indeed it has been asserted that the future of the orange industry of these states is dependent upon the continued coloring of its product.

In 1938 the Congress enacted the present Federal Food, Drug and Cosmetic Act. 52 Stat. 1040; 21 U. S. C. A. §§ 301–392. The adulteration of food in interstate commerce and the introduction of adulterated food into interstate commerce were prohibited. 21 U. S. C. A. § 331. Congressional standards for determining when food would be deemed adulterated were set up.[1] Provisions for tolerances of

[1] "A food shall be deemed to be adulterated—

"(a) (1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health; or (2) if it bears or contains any added poisonous or added deleterious substance which is unsafe within the meaning of Section 406; or (3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or (4) if it has been prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or (5) if it is, in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter; or (6) if its container is

poisonous and deleterious substances were included.[2]

composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health.

"(b) (1) If any valuable constituent has been in whole or in part omitted or abstracted therefrom; or (2) if any substance has been substituted wholly or in part therefor; or (3) if damage or inferiority has been concealed in any manner; or (4) if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.

"(c) If it bears or contains a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by Section 406; *Provided*, That this paragraph shall not apply to citrus fruit bearing or containing a coal-tar color if application for listing of such color has been made under this Act and such application has not been acted on by the Secretary, if such color was commonly used prior to the enactment of this Act for the purpose of coloring citrus fruit.

* * * * *"

[2] 52 Stat. 1046, § 402, 21 U. S. C. A. § 342.

"(a) Any poisonous or deleterious substance added to any food, except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice shall be deemed to be unsafe for purposes of the application of clause (2) of section 402 (a); but when such substance is so required or cannot be so avoided, the Secretary shall promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health, and any quantity exceeding the limits so fixed shall also be deemed to be unsafe for purposes of the application of clause (2) of section 402 (a). While such a regulation is in effect limiting the quantity of any such substance in the case of any food, such food shall not, by reason of bearing or containing any added amount of such substance, be considered to be adulterated within the meaning of clause (1) of section 402 (a). In determining the quantity of such added substance to be tolerated in or on different articles of food the Secretary shall take into account the extent to which the use of such substance is re-

The Secretary of Agriculture, to whom the administration of the Act was originally committed, issued regulations on May 4, 1939, effective May 9, 1939, governing the listing of coal-tar colors.[3] Among those eligible for certification were listed FD&C Orange No. 1, FD&C Orange No. 2, and FD&C Red No. 32.[4] In 1954 the Secretary of Health, Education and Welfare, succeeded to the administration of the Act in the place originally held by the Secretary of Agriculture.[5] The Secretary reached the conclusion that the three colors are not "harmless" as that word is used in Section 406 (b) of the Act. 21 U. S. C. A. § 346 (b). An order promulgating a further regulation[6] was issued by which the three colors were deleted from the list approved for certification for use in foods and in drugs to be taken internally. By Section 701 (f) of the Act,[7] any person who will be adversely affected by an order of the Secretary may file a petition for review with the court of appeals for the circuit wherein such person resides. Petitions for review were filed in three circuits. In the Seventh Circuit the proceeding for review was dismissed. In the Sec-

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quired or cannot be avoided in the production of each such article, and the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances.

"(b) The Secretary shall promulgate regulations providing for the listing of coal-tar colors which are harmless and suitable for use in food and for the certification of batches of such colors, with or without harmless diluents." 52 Stat. 1049, § 406, 21 U. S. C. A., § 346.

[3] 4 F. R. 1935, 1 C. F. R. 1939 Supp. 1214 et seq.

[4] 4 F. R. 3936, 1 C. F. R. 1939 Supp. 1214, 1218.

[5] Reorganization Plan No. 1 of 1953, 67 Stat. 631, 18 F. R. 2053; 67 Stat. 18, 5 U. S. C. A. § 623.

[6] 20 F. R. 8492.

[7] 21 U. S. C. A. § 371 (f).

ond Circuit, by a decision which we shall hereafter discuss, the Secretary's order was affirmed. *Certified Color Industry Committee* v. *Secretary of Health, Education and Welfare,* 2 Cir. 1956, 236 F. 2d 866. Two petitions for review have been filed in this Circuit, one by Florida Citrus Exchange and others, orange growers and packers of Florida and Texas, and the other by Frank R. Schell, the holder of patents on the process for the coloring of citrus fruits with Orange 2 and Red 32. The two proceedings for review in this Court have been consolidated. Red 32 is the only one of the three colors with which we are concerned in this proceeding.

The three colors were on the original list, prepared in 1939, of coal-tar colors available for certification. Some of the coal-tar colors on the list became suspect as toxic and possibly carcinogenic. This prompted further investigation which culminated in the hearings which formed the bases of the order which we here review. At the hearing evidence was introduced that rats did not survive a diet of 1000 parts per million of Red 32. A dog fed 100 parts per million of Red 32 sickened and ultimately died. This was the lowest percentage tested of Red 32. Evidence was introduced at the hearing which showed that Red 32, when used for coloring oranges penetrated the skin for a depth of about 1/1000 of an inch; that peel of the colored orange had from 17.63 to 34.26 parts per million of color; candied orange peel had 7.4 parts per million of color; orange marmalade analyzed 1.8 parts per million of color; and the squeezed juice of colored oranges had a color content range of from 4/100 of one part per million to 7/100 of one part per million. A spokesman for the entire coal-tar color industry stated that the

sale of Red 32 had been discontinued for any purpose except the coloring of oranges. The principal witness for the Secretary was Dr. Vos, Assistant Chief of the Division of Pharmacology of the Food and Drug Administration. He reviewed the tests made upon animals. He testified that on the basis of the experiments and his education and experience he was of the opinion that Red 32 was not a "harmless coal-tar color". On cross-examination he stated that he used the word "harmless" in the absolute sense that the color was capable of producing harm. This was developed by his saying that bad results might follow the taking of two or three ounces of salt but, salt being essential, it would not be regarded as harmful. He had no evidence as to whether the color would produce harmful effects at ordinary levels of use, although he gave an affirmative answer to the question "Aren't the amount and method of proposed use of a material necessary data for deciding whether the material is harmless for the use intended?"

The order of the Secretary which we here review made findings of fact based upon the evidence of the tests of which Dr. Vos testified. At the conclusion of nine paragraphs of specific findings as to the effects of the various quantities of the colors given to animals with mention of one episode of illness resulting to man from eating popcorn colored with Orange 1 where the percentage level did not appear, the Secretary stated:

> "There was no evidence on which findings could be made concerning how much of the three colors is likely to be ingested by man from his food, drugs, and cosmetics. Some interested persons, taking their own products, attempted to show that the amounts ingested would be

> small to the point of insignificance. But those contentions leave aside the occurrence of the colors in the products of others, as well as the fact that upon certification of a color the Department has no means of controlling the amounts of colors used in a variety of food, drugs, and cosmetics. Nor is there authority to limit a color, once certified, to a single food—for example, FD&C Red No. 32 for use in color-added oranges."

By the order it was determined that Red 32 and the other two suspect coal-tar colors were not harmless and suitable for use in food, drugs and cosmetics and these colors were deleted from the approved list. The legal theory upon which the order was based is found in paragraph 2 of the Secretary's conclusions where it was held:

> "Sections 406 (b), 504, and 604 of the Federal Food, Drug, and Cosmetic Act (21 U. S. C. 346 (b), 354, and 364) provide for the listing of coal-tar colors that are harmless and suitable for use in food, drugs, and cosmetics. The act does not provide any method for listing toxic colors for specific food, drug, or cosmetic uses so as to limit their total use to small enough amounts that the toxicity might be disregarded. Under the statute a toxic color cannot be classified as a harmless color."

The primary attack of the petitioners is upon the correctness of the principle as stated in the foregoing quotation.

When the order of the Secretary was entered an effort was made to procure an amendment to the Act to require the Secretary to permit Red 32 to be used in coloring oranges until a more acceptable color should be made available. The amendment as orig-

inally offered was opposed by the Department of Health, Education and Welfare. The measure, as finally agreed upon by its proponents and representatives of the Department, amended Section 402 (c) of the Act by adding thereto the following:

> "Provided further, That this paragraph shall not apply to oranges meeting minimum maturity standards established by or under the laws of the States in which the oranges were grown and not intended for processing (other than oranges designated by the trade as 'packing house elimination'), the skins of which have been colored at any time prior to March 1, 1959, with the coal-tar color certified prior to the enactment of this proviso as FD&C Red 32, or certified after such enactment as External O&C Red 14 in accordance with section 21, Code of Federal Regulations, part 9: And provided further, That the preceding proviso shall have no further effect if prior to March 1, 1959, another coal-tar color suitable for coloring oranges is listed under section 406". 70 Stat. 512; 21 U. S. C. A. § 342 (c).

While this amendment was pending before the House of Representatives where it had its origin,[8] a committee hearing was held. Before the committee was a letter from the Secretary of Health, Education and Welfare where it was stated that the evidence so far available does not establish what the lowest safe dosage of Red 32 would be to test animals, neither does it establish a likelihood of injury to man from the use of the color on the exterior of oranges at the levels of use involved. The studies, said the Secretary, were not designed to determine whether a safe tolerance could be established for a single food, such

[8] H. R. 7732.

as oranges, so that the amounts that might be consumed as color on the exterior surface of oranges would pose no undue risk.' The Commissioner of Food and Drugs appeared and gave a statement at the hearing similar to and in some respects amplifying those contained in the Secretary's letter. He reiterated that the tests made were not designed to learn the effect upon human beings of the minute quantities of the color that might be ingested by its use as an orange coloring. He stated that although the color had been used on oranges since in the early 1930's, no evidence has been found that injury has resulted from the consumption of oranges so colored. This use, said the Commissioner, presented a strong equity for conducting tests. He stated, as did the Secretary, the view of the department that if the color was "harmful" its use must be prohibited and that no tolerances could be fixed.[10] Among the purposes of the amendment, as explained in the report of the Committee of the House of Representatives, was the allowing of time for further exploration of the toxicity of Red 32. In the report it was stated that the practice of coloring the skins of oranges has become an economic necessity for a major segment of the orange industry.[11] In the report of the Senate Committee on Labor and Public Welfare, to whom the bill was referred, the same conclusions were reached.[12] On this factual situation and background we review the order of the Secretary.

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[9] Hearing before a Subcommittee of the Committee on Interstate and Foreign Commerce House of Representatives, 84th Cong., 2d Sess. on H. R. 7732, pp. 2 and 3.

[10] Hearing, supra, pp. 17 and 18.

[11] H. R. Rep. No. 1982, 84th Cong. 2d Sess.

[12] S. Rep. No. 2391, 84th Cong. 2d Sess.

The petitioners list twelve specifications of error upon which they ground their attack upon the Secretary's order. The basic and underlying contention of the petitioners is that the Secretary has erred in construing "harmless", as used in Section 406 (b) of the Act, in an absolute rather than in a relative sense. If the position of the Secretary is correct, he has no choice but to refuse to permit a coal-tar color to be used in food in minute, safe and harmless quantities if, when used in much larger quantities it would or might be injurious or dangerous to health. If the position of the Secretary is correct he has no power to permit a particular coal-tar color to be used for a specific and restricted purpose even though, when so used, it would not be injurious or dangerous to health.

The Secretary has urged that the questions presented for our review are the identical questions which were decided by the Second Circuit in *The Certified Color Industry Committee* v. *The Secretary of Health, Education and Welfare, supra,* and that we should follow that decision unless we are convinced it was clearly wrong. Where an identical issue is presented and no different principle is involved, the decision of another court of appeals is entitled to great weight and affords persuasive argument."[11] Although the appeal in the Certified Color Industry case was from the same order and was upon the same record as the case before us, the identical issue is not presented and a different principle is involved. In the Second Circuit case three coal-tar colors were involved and the uses were all inclusive. The differ-

[11] *Sokol Brothers Furniture Co.* v. *Commissioner of Internal Revenue*, 5 Cir. 1950, 185 F. 2d 222, reh. den. 185 F. 2d 677, cert. den. 340 U. S. 952, 71 S. Ct. 571, 95 L. Ed. 686.

ence was recognized by the Court of Appeals for the Second Circuit. In its opinion it is said:

> "Thus the problem is far different from the one presented recently to Congress when the act was amended to permit the use of Red 32 on orange skins not intended for processing. With only one product contaminated it was not too difficult to argue that such small amounts were involved that a man would have to drink 5000 gallons of orange juice a day before experiencing any adverse effects." 236 F. 2d 871.

The problem we consider is not that which the Second Circuit had and the decision there is, as we hope to show, not in conflict with what we decide here.

In a brief filed with us by amicus curiae, he quotes from a letter to him from the Food and Drug Administration where it was said:

> "Let me say at the outset that this Administration is in agreement with your conclusion that the use of added color is inherently deceptive and is contrary to the interests of both consumers and producers."

This letter is not in the record and would not be the subject of comment by us but for a suggestion that it evidences a hostile and prejudiced attitude of the Food and Drug Administration. We think the record shows the contrary to be the case. It is shown that all oranges to which color is added are so marked and that immature fruit is not colored. The record reflects a departmental attitude of fairness and objectivity, and discloses that the ill-advised statement of the writer of the letter does not express the view of the Secretary or of the department.

It has been contended that the officers charged with the administration of the Act had, from the time the

Act was passed until the time of the investigation which culminated in the hearings and in the order we here review, construed the Act as permitting, if not requiring, the fixing of tolerance for harmless uses of Red 32. Such administrative construction should be persuasive, so we are told, if not binding as an administrative construction of an ambiguous provision. The Secretary, on the other hand, asserts that the administrative interpretation has not altered, and that the change of position resulted from the different findings of fact required by the recent investigations and experiments. We need not pursue this inquiry. An administrative construction which is clearly erroneous is not binding on the administrative agency nor is it persuasive in judicial proceedings,[14] and this should be particularly true where the purpose of the Act is to protect the health of the public.[15] The doctrine of giving weight to an administrative construction of a statute does not apply to an administrative determination of the administrator's statutory powers.[16] This, in essence, is one of the questions before us.

The decision we are to make is whether the Secretary of Health, Education and Welfare is required or permitted to determine if there is a minimum quantity of the coal-tar color designated as FD&C Red No. 32 which can be used in adding color to the skins of mature oranges without danger of impairing the health of those who consume such oranges; and if so required or permitted, and if it be determined that

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[14] 82 C. J. S. 771, Statutes § 359 b.

[15] The purposes of the Act are discussed *infra*.

[16] *Stark* v. *Brannan*, D. C. D. C. 1949, 82 F. Supp. 614, aff. 87 U. S. App. D. C. 388, 185 F. 2d 871, aff. 342 U. S. 451, 72 S. Ct. 433, 96 L. Ed. 497.

there is such minimum, should the Secretary list and certify such color for such use. In the construction of statutes courts will look to the entire act and to its objects and policy.[17] Results which are incongruous [18] or absurd [19] are to be avoided. Where a particular construction of a statute will occasion great inconvenience or produce inequality and injustice, that view is to be avoided if another and more reasonable interpretation is present in the statute.[20] In the construction of a legislative measure, statutes in pari materia, amendatory acts, and their legislative history may be examined.[21] These rules are the primary guides to our solution of the problem before us.

In the leading and often cited Lexington Mill case [22] the Supreme Court declares the purpose of the Act, saying:

> "The statute upon its face shows, that the primary purpose of Congress was to prevent injury to the public health by the sale and transportation in interstate commerce of misbranded and adulterated foods. * * * As against adulteration, the statute was intended to protect the

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[17] *Mastro Plastics Corporation* v. *National Labor Relations Board*, 350 U. S. 270, 76 S. Ct. 349, 100 L. Ed. 309, *National Labor Relations Board* v. *Lion Oil Co., et al*, 352 U. S. 282, 77 S. Ct. . . . ., 1 L. Ed. 2d 331; *United States* v. *Witkovich*, 353 U. S. 194, 77 S. Ct. . . . ., 1 L. Ed. 2d 765.

[18] *National Labor Relations Board* v. *Lion Oil Co., et al*, *supra*.

[19] *United States* v. *American Trucking Associations, Inc.*, 310 U. S. 534, 60 S. Ct. 1059, 84 L. Ed. 1345; *Fulford* v. *Forman*, 5 Cir. 1957, ... F. 2d . . . . .

[20] *Knowlton* v. *Moore*, 178 U. S. 41, 20 S. Ct. 747, 44 L. Ed. 969.

[21] *United States* v. *Freeman*, 44 U. S. (3 How.) 556, 11 L. Ed. 724.

[22] *United States* v. *Lexington Mill & Elevator Co.*, 232 U. S. 399, 34 S. Ct. 337, 58 L. Ed. 658.

public health from possible injury by adding to articles of food consumption poisonous and deleterious substances which might render such articles injurious to the health of consumers." 332 U. S. 409.

The purpose to protect the public health is an important aim of the statute,[23] and touches phases of the lives and health of people which are largely beyond self-protection.[24]

We are here reviewing the order of the Secretary only with respect to the coal-tar color FD&C Red No. 32 as used in the coloring of the skins of oranges. If there be other like situations, then of course that which we hold will be applicable to them. We are not confronted with the broad questions which were before the Second Circuit in the *Certified Color Industry* case, *supra*.

In some of the cases[25] the de minimis doctrine has been recognized as applicable or has been applied in adulterated food cases. The contentions of the petitioners suggest that they regard the doctrine applicable here. Neither the Secretary's findings nor the evidence on which they were based calls for any consideration of the doctrine upon the record before us.

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[23] *United States* v. *Coca-Cola Co.*, 241 U. S. 265, 36 S. Ct. 573, 60 L. Ed. 995.

[24] *United States* v. *Dotterweich*, 320 U. S. 277, 64 S. Ct. 134, 88 L. Ed. 48, reh. den. 320 U. S. 815, 64 S. Ct. 367, 88 L. Ed. 492; *62 Cases of Jam* v. *United States*, 340 U. S. 593, 71 S. Ct. 515, 95 L. Ed. 566.

[25] *United States* v. *449 Cases*, 2 Cir. 1954, 212 F. 2d 567, 45 A. L. R. 2d 846; *333 Cartons* v. *United States*, 4 Cir. 1947, 165 F. 2d 728; *A. O. Andersen & Co.* v. *United States*, 9 Cir. 1922, 284 F. 542; *United States* v. *298 Cases*, D. C. Ore. 1949, 88 F. Supp. 450; *United States* v. *184 Barrels*, D. C. E. D. Wis. 1943, 53 F. Supp. 652; *United States* v. *133 Cases*, D. C. E. D. Pa. 1938, 22 F. Supp. 515.

The words "harm", "harmful", and "harmless" are terms of relation. In this sense they resemble "wrong" and "wrongful".[26] Red 32 is harmless, i. e. not harmful, to all persons under the protection of the Act while it remains in the vat or the vial. An injury must occur before harm results. The color Red 32 becomes harmful, i. e. not harmless, when it is consumed, and then only if consumed in such quantity that injury or harm might result. If there can be a use of the color in such small quantities that it can be consumed without risk of injury or harm then, in such quantities, it is harmless. A person is as unharmed after consuming a minute harmless quantity of Red 32 (if such there be) as he would be had he consumed none of it.

In *United States* v. *Lexington Mill & Elevator Co., supra,* the Supreme Court reviewed the condemnation of a lot of flour to which had been added a poisonous ingredient but in a quantity so small that the health of a consumer could not be thereby injured. The statute then provided that an article of food should be deemed to be adulterated if it "contain any added poisonous or other added deleterious ingredient which may render such article injurious to health". It was contended there, as it is contended here, that it is the character—not the quantity—of the added substance which is to determine the case. This contention was rejected. The Court said:

> "If it cannot by any possibility, when the facts are reasonably considered, injure the health of any consumer, such flour, though having a small addition of poisonous or deleterious ingredients, may not be condemned under the act." 232 U. S. 411.

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[26] Cf. *Palsgraf* v. *Long Island Railroad Co.*, 248 N. Y. 339, 162 N. E. 99, 59 A. L. R. 1253.

As in the *Lexington Mill* case, it was held in the Seventh Circuit that "injurious" is a relative rather than an absolute term. *W. B. Wood Mfg. Co.* v. *United States,* 7 Cir. 1923, 286 F. 84. We think "harmless" is also to be so construed.

The Secretary would concede, apparently, the possibility that a person might consume Red 32 in such small quantities that no hazard to health would result. His guarded statement is that "the evidence so far available does not establish a likelihood of injury to man from the minute amount likely to find its way into the human diet from the consumption of such colored oranges at the level of use involved."[27] The Commissioner of Food and Drugs has admitted that there was no evidence of injury to consumers of colored oranges.[28] The Secretary has made no effort to ascertain whether or not there is, in fact, any likelihood of injury to the health of persons who consume oranges colored with Red 32. Taking the position that no quantitative test is authorized, the Secretary disclaims any power to fix a tolerance for the use of Red 32 in the coloring of oranges or for any other particular use. Under this theory it would make no difference whether or not there was a minimum quantity of Red 32 which would not be injurious. Malum in uno, malum in omnibus, is the departmental canon of construction.

Unless the quantities of Red 32 used in the coloring of oranges are dangerous to public health, the objects and purposes of the Act will not be promoted by a construction which prohibits that use in such quantities. The statute which we construe provides for the fixing of tolerances for added poisonous and deleterious

[27] Hearing, supra, p. 3.

[28] Hearing, supra, p. 18.

substances required in the production of food [29] and, by a 1954 amendment,[30] for the fixing of tolerances for poisonous pesticides on raw agricultural commodities. We cannot see how the objects and purposes of the statute would be furthered by a construction which permits safe, i. e. harmless, quantities of poisons other than coal-tar colors to be added to food where required in its production, and which permits safe tolerances of poisons for pesticides, but prohibits the use of a coal-tar color in the most minute and harmless quantity because it is harmful and injurious in large quantities. Such a construction would be an unwarranted discrimination, not so much against the coal-tar color and the manufacturers of it, but against that important segment of the orange producers who are economically dependent upon it. The construction of the Secretary results, or may result, in inequality and injustice. There is, we think, a more reasonable interpretation in the Act.

The Secretary found that Red 32 is toxic; in other words that it is poisonous. The evidence justified the finding. If the Secretary is correct in his construction of "harmless", Section 402 (a) of the Act is inapplicable to coal-tar colors. If his construction is erroneous, Section 402 (a) would apply. If Section 402 (a) applies, the colored oranges would be "adulterated" only if the added poisonous substance was unsafe within Section 406 (a). Under this section poisonous substances are permitted to be added to food if it "is required in the production thereof" within such limits as to quantity or extent as the Secretary finds necessary for the protection of public health. The Committees of the Senate and the House of Representatives each found that the practice of

[29] 21 U. S. C. A. § 346 (a).
[30] 68 Stat. 511, 21 U. S. C. A. § 346 a.

coloring oranges has become an economic necessity for a major segment of the orange industry since a high percentage of the oranges grown in Florida and Texas would meet with strong consumer resistance if not colored.[31] It is as important for a food to be marketable as for it to be palatable and, if the findings of the Committees be correct, then the addition of color is "required in production", as that phrase is used in the Act. Section 402 (a) and Section 402 (c) are not mutually exclusive. A coal-tar color may not be added unless from a certified batch. By Section 406 (b) only those coal-tar colors may be certified which the Secretary has listed as harmless. The Secretary and his colleagues in the Department did not oppose the enactment of the 1956 amendment to Section 402 (c). A reason given was that during the period of the moratorium a "non-toxic color" might be developed. It is the contention of the petitioners that no colors other than Red 32 and the others banned by the Secretary's order are effective. If another color be found which is not a coal-tar color but is as much or more toxic, then we see no reason to doubt that the Secretary would be required to deal with it under Section 406 (a) and to provide tolerances for its use in the event it could be used in any limited quantity without being injurious to the public health. The Secretary, in his order, has stated that "the Department has no means of controlling the amounts of colors used in a variety of fooods, drugs and cosmetics". It is not apparent that this is a problem with respect to other toxic substances which are added to foods under tolerances fixed by the Secretary and nothing is shown to indicate that it would be a problem in dealing with a coal-tar color. We see no reason for supposing that Congress intended to permit the use of toxic sub-

[31] S. Rep. No. 2391, supra; H. R. Rep. No. 1982, supra.

stances, including toxic colors other than coal-tar products, in safe and harmless quantities and to prohibit the use of toxic coal-tar colors in safe and harmless quantities. We do not ascribe such an intention to Congress. Another reason given by the Secretary for not opposing the 1956 amendment was that the moratorium for Red 32 would permit further exploration of its toxicity. It is the view of the Secretary that if it be found that the coloring of oranges with Red 32 is not injurious to humans and can be continued with safety, further legislation will be required. With this conclusion we do not agree.

We construe the Act as requiring the Secretary, under Section 406 (a), to determine whether the use of the color Red 32 is required in the production for market of oranges grown by a substantial segment of the orange producing industry; and if he finds that such use is so required, then to determine the quantity, if any, that can be tolerated as safe, and by regulation to limit the quantity to such extent as he finds necessary for the protection of public health. With "harmless", as used in Section 406 (b), construed as a relative rather than an absolute term, regulations promulgated by the Secretary under that section as well as under Section 406 (a) could be issued if the prerequisite findings as to the necessity for using color had been made and the tolerance limits had been fixed.

In the order of the Secretary it is stated that there is no "authority to limit a color, once certified, to a single food—for example, FD&C Red No. 32 for use in color-added oranges". Although there may be no express statutory provision authorizing the limiting of the use of a color to a single food, it is not prohibited. If the adding of a toxic substance to one food may be harmful, but harmless when added to another food in limited quantities fixed by a predetermined tolerance,

we are of the opinion that the Secretary is empowered to permit its use in the latter instance. The Secretary at one time seemed of the same opinion. In the Food and Drug Administration Regulations promulgated in 1955, a number of coal-tar colors were listed for certification for use in food, drugs and cosmetics. Among these are colors designated as "lakes". The regulations provide that "No lake listed in paragraph (a) of this section shall be certified for any use in food except external application to shell eggs."[32] We shall not indulge in speculation upon the comparative porosity of egg shell and orange peel. We merely observe that the Secretary restricted the use of a group of coal-tar colors to a single food, and we think he was fully empowered to do so.

We are not unmindful of the admonition of the Second Circuit in the *Certified Color Industry* case, *supra*, that:

> "Now that their toxicity has been amply demonstrated it would be unconscionable for any court to require the Secretary to permit their use without the clearest and most uncompromising evidence that usage at certain levels was absolutely safe." 236 F. 2d 870.

With this statement we are in accord. The findings of fact are to be made by the Secretary. Such findings, under Section 701 (f) (3) of the Act,[33] are conclusive if supported by substantial evidence.[34] We again advert to the Secretary's letter to the Chairman of the Committee of the House of Representatives at the time it was considering the 1956 amendment. The Secretary said:

> "While the scientific evidence so far available does not establish what the lowest safe dosage

[32] 20 F. R. 9554, 21 C. F. R. § 9.3 (c).

[33] 52 Stat. 1055, 21 U. S. C. A. § 371 (f) (3).

[34] See *Byrd* v. *United States*, 5 Cir. 1946, 154 F. 2d 62.

> would be to test animals, neither does it establish a likelihood of injury to man from the use of this color [Red 32] on the exterior of oranges at the levels of use involved. Before final conclusions can be drawn on this point, however, it is necessary to conduct adequate scientific studies of chronic toxicity on laboratory animals over their life span, which will involve feeding tests at levels related to the quantities of such externally applied color that might enter man's diet. Such tests and studies will require approximately 3 years. We assume that the industry will make such studies." [35]

Since the Secretary is authorized by Section 702 (a) of the Act [36] to conduct examinations and has a technical staff already familiar with the problem, we think it not amiss, in view of our decision here, that we suggest consideration be given by the Department to continuing or resuming the tests and studies from which the evidence was obtained which was adduced before the departmental hearing.

In the *Certified Color Industry* case, *supra*, the court rejected the Secretary's construction of the word "harmless". It holds that the government need not prove that a coal-tar color is in fact injurious to health but it is enough if it shows that it "might render the article of food injurious," adopting the quoted words from the *Lexington Mill* case. Because, in the quantities tested, the possibility of injury to health was indicated, the court sustained the order. It held that "under the circumstances disclosed in the record" the petitioning manufacturers of coal-tar colors could not require the Secretary to establish tolerances fixing safe levels of use. For this position two reasons were assigned, first that safe levels have not been established,

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[35] Hearing, *supra*, p. 3.

[36] 52 Stat. 1056, 21 U. S. C. A. § 372 (a).

and second, the department could not control uses within tolerance limits if such limits were prescribed. In connection with the first of these grounds the court comments that the industry made no investigation as to the effect of the colors at low levels of usage. The record bears out the court's observation, but under the Secretary's construction of the Act the effect of the colors at minimal levels would be immaterial. The inability to control the quantity used is no different, as we see it, in dealing with a coal-tar color than with respect to other toxic or poisonous substances where the Secretary is required to establish tolerances. In any event, as the court in the *Certified Color Industry* case points out, the situation before it was different from the case of a single color such as Red 32 applied to a single use such as the colorings of oranges. Such a case is the one before us.

After a hearing in 1939 Red 32 was found to be harmless and suitable for use in foods, drugs and cosmetics. The situation as presented on this review was briefly and accurately characterized in a letter from the Commissioner of Food and Drugs to Florida Senators and Congressmen written February 8, 1955. In speaking of Red 32 the Commissioner said:

> "Recent investigations show that these colors when fed in substantial amounts, show evidence of toxicity. There is, however, no evidence that, in the amounts used, and in the manner of use, in the coloring of citrus fruit, the product so colored is not safe for human consumption."

Unless there is evidence that, in the amounts used, and in the manner of use, oranges colored with Red 32 are unsafe for human consumption, the 1939 finding should not be supplanted by a contrary ruling by which such use is prohibited. It may be parenthetically observed that "unsafe" is the yardstick for de-

termining tolerances under Section 406 (a). A determination may be made by the Secretary on his own initiative or upon the petition of any interested person." as to whether coloring is required and, if so, as to whether Red 32 is a harmless coal-tar color for use in coloring oranges and to fix the tolerances, if any, as may be proper for such use.

At the outset of this proceeding, upon agreement, a stay order was entered to permit the use of Red 32 in coloring oranges while the proceeding was pending. Except as to duration, the substance of the stay order's provisions is followed in our disposition of the matter.

The order promulgated by Marion B. Folsom, Secretary of Health, Education and Welfare, on November 10, 1955, published in the Federal Register on November 16, 1955, (20 F. R. 8492) will be set aside in so far as said order removes the coal-tar color FD&C Red No. 32 from the list of colors which may be certified for use in coloring the skin of oranges meeting minimum maturity standards prescribed in the State of Florida and Texas; *provided,* that nothing herein or in the judgment of this Court entered pursuant hereto shall restore said coal-tar color to the list of colors which may be certified for unrestricted use in food, drugs and cosmetics but shall operate to authorize the certification of batches of said color conforming to the specifications for the color appearing at 21 C. F. R. 135.3 (1949 ed.) for the purpose of coloring the skin of mature oranges only; *provided further,* that the Secretary shall be required to certify only sufficient batches of FD&C Red No. 32 as may be necessary to color the skin of mature oranges from time to time; *provided further,* that the certificates issued for batches of FD&C Red

[17] 52 Stat. 1055, 21 U. S. C. A. § 371 (e).

No. 32 may be limited by their certificate for use in coloring mature oranges only; *and provided further,* that nothing herein or in the judgment of this Court entered pursuant hereto shall be deemed to restrict the Secretary from making further investigations and conducting hearings for a determination of whether the use of Red 32 is required in the production of oranges and to determine the tolerances, if any, that are safe and harmless, as harmless is herein construed and defined.

Judgment accordingly will be entered setting aside in part, as herein set forth, the aforesaid order of the Secretary.

HUTCHESON, Chief Judge, Dissenting:

I am of the clear opinion that the result reached and the conclusions stated by the majority are unwarranted in law, and also, with respect to the findings of the Secretary of Agriculture, represent a case of judicial fiating which, though it has sometimes found favor in other courts (Cf. *Quaker Oats* v. *Security,* 129 F. (2) 76, reversed 318 U. S. 218), has not until now found favor here. Cf. *Byrd* v. *U. S.,* 154 F (2) 62.

Because I am of this opinion, I feel constrained not only to note my dissent but to point out as briefly and as effectively as I can the patent errors on which the opinion proceeds. Because, too, it is clear to me that, while certainly presenting matters material for legislative consideration, it as certainly does not present matters material to the determination of the issue presented here, which is not what the law ought to be but what it is, I pass, with no more than comment, the basic assumption of the opinion, that the effect upon the future of the industry of our construction of the statute is the controlling consideration

in this case, to go at once to the controlling issues which are presented for decision here.

The first of these, as stated on page 12 of the majority opinion, is whether the questions presented for our review are the identical questions which were decided by the Second Circuit in the *Certified Color Industry Committee* v. *Secretary of Health, Education and Welfare* (2 Cir) 1956, 236 F (2) 866.

The second, as the majority opinion states it on page 15 is "whether the Secretary of Health, Education and Welfare is required or permitted to determine if there is a minimum quantity of the coal-tar color, designated as FD&C Red #32, which can be used in adding color to the skins of mature oranges without danger of impairing the health of those who consume such oranges, and, if so required or permitted and if it be determined that there is such a minimum, should the Secretary be required to list and certify such color for such uses".

The third and last, as stated on page 24 of the majority opinion, is whether "If it be found that the coloring of oranges with Red 32 is not injurious to humans and can be continued with safety, further legislation will be required".

I take up these questions in turn to say of the first that I not only find myself in complete agreement with the respondent's position that the decision in the *Certified Color* case is in point, is correct, and should be followed here, but I find completely unconvincing the arguments of the majority in support of its contrary view, that the case is not in point. Indeed, it seems to me that the fact alone that the orange industry was not a party to the appeal in the *Certified Color* case is, from the standpoint of that case as a precedent, as completely insubstantial as the classic

difference claimed to exist between a white and a black horse case.

In short, the test of what was at issue and decided in, and what was the effect of, the decision in the *Certified Color* case, as compared to this one, is to be found in a resort to the opinion in that case. Such a resort will show that the precise question here argued, the meaning and effect of the statute, was determined not with particular reference to the nature and character of the business of particular appellants but upon the basis of a construction of the present statute as compared to former statutes, in the light of the decisions construing and applying them. With deference, the majority has completely misread and misapplied the statement in the opinion in the *Certified Color* case at p. 871, "*Thus the problem is far different from the one presented recently to Congress when the act was amended to permit the use of Red 32 on orange skins not intended for processing*" (emphasis supplied).

In making this statement, the court was not, as the majority in this case seems to think it was, stating that, as applied to oranges, *the construction of the statute under review and the duty of the secretary under it* would be different from the construction of the statute and the duty of the secretary as applied to products generally. In making the statement the court was stating correctly that, viewed from the standpoint of legislative relief by amendment, the problem presented was different from the one presented to the secretary in proceeding under, and the courts in construing, the statute before it was amended. The court was not at all suggesting that the existing statute gave the secretary any different discretion or authority in respect to oranges than in respect to other products. To have so held would have been in

effect to hold that the statute under review here gave the secretary authority in his discretion to consider and determine, product by product, whether he could and should establish tolerances, and this in the face of a statute containing no such language and differently construed both by the Executive or the Legislative branch.

In its treatment of the second question, the majority, acting under the influence of the same idea which dictated its rejection of the result and the reasoning in the *Certified Color* case, that the situation and needs of the Texas and Florida orange industry make a special case out of their complaint and requires a construction of the statute based not upon the language used but upon general legislative considerations as to what such an act ought to provide, draws for the support of its view upon the *Lexington Mill* case, *U. S.* v. *Lexington Mill & Elev. Co.*, 232 U. S. 399, decided under an entirely different statute, that of 1906, and containing entirely different provisions from those under construction here. It seems clear to me that no sound reason is presented, and no support is found in either the language, the legislative history of the statute under construction, or the authorities cited, for the view of the majority that the Secretary's finding, quoted fully with approval in the *Certified Color* case at p. 871, was wrong and must be set aside.

Finally, while the answer of the majority, to the third and final question, whether the needs of the industry can be taken care of without additional legislation, that it can be, follows naturally enough from what has gone before, it seems clear to me that it is nothing more than a complete tour de force, the substitution of judicial for congressional legislation. Though the Executive and Legislative branches of the

government have determined that the 1956 amendment to Sec. 402 (b) was necessary in order to give the secretary the power to determine tolerances as to coal tar products, the court, differing with both, has held that it can and should by its order in effect say, we will construe the statute, and by order give effect to our construction, so as to make unnecessary, indeed useless, the 1956 amendment or any future congressional legislation, and with the Secretary thus panoplied in the judicial fiat as to his authority under the statute before its amendment, and compelled by the judicial order to give that fiat effect, Congress, the Secretary and the Texas and Florida Industries need trouble themselves no more, but, resting securely upon the judicial legislation and order, they may all go about their business in the future untroubled and undisturbed.

It is one thing for a court to construe a statute. It is quite another for it to rewrite it. I respectfully dissent from what I regard here not as a construction but a rewriting of the statute.

JUDGMENT

Extract from the Minutes of July 12, 1957.

No. 15934

FLORIDA CITRUS EXCHANGE, ET AL.

v.

M. B. FOLSOM, SECRETARY OF THE DEPARTMENT OF HEALTH, EDUCATION AND WELFARE

This cause came on to be heard on the petition of Florida Citrus Exchange, and others, for review of an order of the Secretary of Health, Education and

Welfare issued on November 10, 1955, and was argued by counsel;

On consideration whereof, it is now here ordered, adjudged and decreed by this Court that the order of the Secretary in this cause be, and the same is hereby, set aside in part, in accordance with the opinion of this Court.

"HUTCHESON, Chief Judge, dissenting."

JUDGMENT

Extract from the Minutes of July 12, 1957.

No. 15948

FRANK R. SCHELL

v.

M. B. FOLSOM, SECRETARY OF THE DEPARTMENT OF HEALTH, EDUCATION AND WELFARE

This cause came on to be heard on the petition of Frank R. Schell, for a review of an order of the Secretary of Health, Education and Welfare issued on November 10, 1955, and was argued by counsel;

On consideration whereof, It is now here ordered, adjudged and decreed by this Court that the order of the Secretary in this cause be, and the same is hereby, set aside in part, in accordance with the opinion of this Court.

"HUTCHESON, Chief Judge, dissenting."

In the United States Court of Appeals for the Fifth Circuit

No. 15934

FLORIDA CITRUS EXCHANGE, ET AL., APPELLANTS

v.

M. B. FOLSOM, SECRETARY OF THE DEPARTMENT OF HEALTH, EDUCATION AND WELFARE, APPELLEE

No. 15948

FRANK R. SCHELL, APPELLANT

v.

M. B. FOLSOM, SECRETARY OF THE DEPARTMENT OF HEALTH, EDUCATION AND WELFARE, APPELLEE

ON PETITIONS FOR REVIEW OF AN ORDER OF THE SECRETARY OF HEALTH, EDUCATION AND WELFARE

(August 28, 1957)

ON PETITION FOR REHEARING

Before HUTCHESON, Chief Judge, and JONES and BROWN, Circuit Judges.

Per Curiam.

It is ordered, That the petition for rehearing in the above entitled and numbered causes be, and it is, hereby denied.

HUTCHESON, Chief Judge, Dissenting.

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In the Supreme Court of the United States

OCTOBER TERM, 1958

No. 27

MARION B. FOLSOM, SECRETARY OF HEALTH, EDUCATION AND WELFARE, PETITIONER,

v.

FLORIDA CITRUS EXCHANGE, FRANK R. SCHELL, ET AL.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

BRIEF FOR THE PETITIONER

OPINIONS BELOW

The opinions in the Court of Appeals are reported at 246 F. 2d 850. (R. 168-191). The Secretary's order (R. 158) appears in 20 F.R. 8493.

JURISDICTION

The judgments of the Court of Appeals were entered on July 12, 1957 (R. 191-192). A motion for rehearing before the court *en banc* was denied on August 28, 1957, Chief Judge Hutcheson dissenting (R. 192). On November 27, 1957, by order of Justice Black, the time for filing a petition for a writ of certiorari was extended to and including January 3, 1958 (R. 260). The petition for a writ of certiorari was filed on January 3,

1958, and was granted on March 17, 1958 (R. 260). The jurisdiction of this Court rests on 28 U.S.C. 1254 (1) and Section 701(f)(4) of the Federal Food, Drug, and Cosmetic Act of June 25, 1938, 52 Stat. 1040, 1056, 21 U.S.C. 371(f)(4).

QUESTIONS PRESENTED

1. Whether the court below erred in directing the Secretary of Health, Education, and Welfare to certify as harmless for use in the coloring of oranges a coal-tar color which admittedly has been properly found to be poisonous and properly decertified for general use under Section 406(b) of the Federal Food, Drug, and Cosmetic Act.

2. Whether the provisions of Section 406(a) authorizing the Secretary to establish tolerances for use of poisonous substances in food, when required in production, applies to coal-tar colors found not to be harmless under Section 406(b).

3. Whether "required in the production," as used in Section 406(a), means required in post-harvest treatment of oranges for greater eye-appeal in the market place.

4. Whether, assuming that the Secretary has power to establish tolerances for use of poisonous coal-tar color on oranges, it was proper for the Court of Appeals to assume that *prima facie* the coloring for oranges was required in production, and not dangerous in that particular use, and thus to cast the burden on the Secretary to show that the use was dangerous to the health of man before he could remove the coal-tar color from the list of approved colors.

STATUTE INVOLVED

The Federal Food, Drug, and Cosmetic Act, as amended, 52 Stat. 1040, 70 Stat. 512 (21 U.S.C. 301 *et seq.*), provided in pertinent part as follows:

Sec. 402. A food shall be deemed to be adulterated—

(a)(1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health; or (2) if it bears or contains any added poisonous or added deleterious substance which is unsafe within the meaning of section 406; * * *

* * * * *

(c) If it bears or contains a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by section 406 * * * *Provided further,* That this paragraph shall not apply to oranges meeting minimum maturity standards established by or under the laws of the States in which the oranges were grown and not intended for processing (other than oranges designated by the trade as "packing house elimination") the skins of which have been colored at any time prior to March 1, 1959, with the coal-tar color certified prior to the enactment of this proviso as FD&C Red 32, or certified after such enactment as External D&C Red 14 in accordance with section 21, Code of Federal Regulations, part 9: *And pro-*

vided further, That the preceding proviso shall have no further effect if prior to March 1, 1959, another coal-tar color suitable for coloring oranges is listed under section 406 [21 U.S.C., Supp. V, 342].

* * * * * *

Sec. 406 (a) Any poisonous or deleterious substance added to any food, except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice shall be deemed to be unsafe for purposes of the application of clause (2) of section 402 (a); but when such substance is so required or cannot be so avoided, the Secretary shall promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health, and any quantity exceeding the limits so fixed shall also be deemed to be unsafe for purposes of the application of clause (2) of section 402 (a). * * * In determining the quantity of such added substance to be tolerated in or on different articles of food the Secretary shall take into account the extent to which the use of such substance is required or cannot be avoided in the production of each such article, and the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances.

(b) The Secretary shall promulgate regulations providing for the listing of coal-tar colors which are harmless and suitable for use in food and for the certification of batches of such colors, with or without harmless diluents [21 U.S.C. 346].

* * * * * *

Sec. 701 (f) (1). In a case of actual controversy as to the validity of any order under subsection (e), any person who will be adversely affected by such order if placed in effect may at any time prior to the ninetieth day after such order is issued file a petition with the United States Court of Appeals for the circuit wherein such person resides or has his principal place of business, for a judicial review of such order * * *.

* * * * *

(3) The court shall have jurisdiction to affirm the order, or to set it aside in whole or in part, temporarily or permanently. * * * The findings of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive.

(4) The judgment of the court affirming or setting aside, in whole or in part, any such order of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari * * * [21 U.S.C. 371].

STATEMENT

The Secretary of Health, Education, and Welfare, after public procedings and on the basis of uncontroverted evidence, issued a final order on November 10, 1955, removing coal-tar colors[1] FD&C Orange No. 1, Orange No. 2, and Red No. 32 from the approved list

[1] "Coal-tar colors" are synthetic dyes, derived actually or theoretically from coal tar, which are widely used in coloring many foods, drugs, and cosmetics, 21 C.F.R. § 9.1, 20 F.R. 9554 (Dec. 20, 1955). "Coal tar" is the brown or black viscous liquid produced in connection with the destructive distillation of coal (Encyclopedia of Chemical Technology, Vol. 13, p. 614 (1954)). Coal tar is a by-product of coke production.

of harmless colors for unrestricted use in food, drugs, and cosmetics (R. 158.)

This rule-making order was reviewed generally and upheld by the Second Circuit in *Certified Color Industry Committee* v. *Secretary of Health, Education, and Welfare*, 236 F.2d 866. It was reviewed and held invalid, insofar as it concerns Red No. 32 as used for coloring oranges in Texas and Florida, by the court below in this case (R. 168-191). 246 F. 2d 850.

A: The Secretary's Order:

1. Red 32 had been placed on the approved list for use in food, drugs, and cosmetics in 1939, after a public hearing at which its harmlessness was apparently established. 4 F.R. 3931, 3936 (Finding 34). New investigations by the Department of Health, Education, and Welfare were initiated after scientific questions as to the possible carcinogenicity of Red 32 and other coal-tar colors had been raised. These investigations were spurred by the Hearings before a Select Committee of the House of Representatives to Investigate the Use of Chemicals in Food Products.[2] The investigations, conducted with small laboratory animals (rats and dogs) which could be kept under careful observation during their life-time and sacrificed for careful post-mortem examination, were begun in 1951 and completed in 1953 (R. 206-209, 217, 219, 220-221, 241-252, 254-259). The result established to the satisfaction of

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[2] See the opinion below, R. 172, 246 F.2d 850, 853; *Certified Color Industry Committee* v. *Secretary*, 236 F.2d 866, 867 (C.A. 2), Hearings, Select Committee, 81st Cong., 2d Sess. (pursuant to H. Res. 323), pp. 229, 238; 82d Cong., 1st Sess. (pursuant to H. Res. 74), part 1, pp. 325, 326, 332, 334; 2d Sess. (pursuant to H. Res. 74 and 447), part 3, pp. 1353-1355, 1360, 1363, 1369, 1381.

trained toxicologists that the three colors involved in the instant order (Red 32, Orange 1, and Orange 2) have significant toxicity.

Upon completion of the investigations, the results were given to the certified color industry (R. 226), and the Department announced that a hearing would be held with a view to removing Red 32 and the other two colors from the list of harmless colors. At the hearing, the sole scientific witness for the color industry stated that the industry had no pharmacological data of its own to present, that the industry had done no such work since 1939, and that it was "willing to accept the result of the studies made by the Food and Drug Administration" (R. 226-228). The Florida Citrus Commission also indicated that it did not oppose "any action which the Secretary may deem advisable on the basis of the record" (R. 224).

Of the scientific investigations, the court below said: "The Secretary found that Red 32 is toxic; in other words that it is poisonous. The evidence justified the finding." R. 182, 246 F. 2d at 859.[3] The Secretary's detailed findings of fact reveal that Red 32 is the most toxic of the three colors. Pharmacological studies established that at 0.5% and 0.25% in the diet of test rats (5,000 to 2,500 parts per million (ppm)) the color killed most of the rats in a short time (R. 242). 0.1% (1,000 ppm) had the same, but a less rapid, effect (R.

[3] The Second Circuit, in evaluating the record, held that the overwhelming weight of the evidence had shown that the three colors might render food in which they were used injurious to health. It pointed out that the least toxic of the three had serious immediate effect on man and that the overall effect on the laboratory animals by proof on autopsy was alarming. "Consequently", it said, "the delisted colors are not 'harmless' within the meaning of Section 406(b)." 236 F. 2d 866, at 870.

242). On autopsy, the animals had liver damage, anemia, and enlargement of the right side of the heart [4] (R. 242-243, 246-249, 250-251). In dogs, 0.04% (400 ppm) caused deterioration, weight loss, sporadic diarrhea, moderate atrophy of vital organs and muscular dystrophic changes (R. 255-259). One dog at 0.01% (100 ppm), the lowest test dosage fed, lost weight and died (R. 254). A single oral dose of 100 milligrams (about 1/3 the weight of an ordinary 5 grain aspirin tablet) produced diarrhea (R. 259). (R. 158, 163, Findings 7-8).

The Secretary found the evidence inadequate to support findings as to the amounts of color likely to be ingested by man from his food, drugs, and cosmetics (R. 164, Finding 10). The industry committee representative testified that his company (one of the largest in the business) had done no work to learn how much of these colors is found on various foods, including oranges and products made from orange peel (R. 228). The Florida Citrus Commission did, however, present analyses based on samples drawn from "two boxes of color-added pineapple oranges" (R. 225).

The Secretary concluded both (1) that he had no statutory authority under Section 406(b) of the Federal Food, Drug and Cosmetic Act to list colors of established toxicity and then attempt by regulation to restrict the levels of use of these poisonous colors in selected foods, drugs, and cosmetics as a means of protecting the public from the consumption of harmful amounts of the toxic colors; and (2) that no safe level

[4] No heart damage was found in rats fed 0.25% (2,500 ppm); yet at 0.1% (1,000 ppm) heart damage was definitely shown. The pathologist remarked on the fact of the lower dosage "showing a constant effect of the dye feeding on the heart" (R. 250-251).

of administration was found, even in test animals, for Red 32[5] (R. 164-165; Conclusions 1-2).

2. Petitions asking the Secretary to reopen the hearing were made by the Certified Color Industry Committee (R. 152), and Frank R. Schell (R. 116). Their purpose was to offer evidence to establish that the amounts of the three colors normally used in a variety of foods and drugs were substantially less than the lowest level of internal administration that caused damage to test animals (R. 152). More particularly, respondent Schell offered to prove that Red 32 is not dangerous to human health since there has been no evidence of injury to industrial workers in frequent contact with the color, and that the animal feeding tests in the record were of no significance because the amounts fed were far in excess of the amounts of color man would get from color-added oranges (R. 118-119). The aim was to show that the amounts of color normally used are wholly insignificant from a toxicological standpoint, and at least that safe tolerances could be established for the three colors in a number of foods and drugs, including oranges.

The Secretary refused to reopen (R. 154-157). His reasons were that the animal data failed to establish a safe level of dosage for Red 32 for the test animals; that man is more susceptible than the test animals, making it impossible to transpose the animal data directly to man; and that Red 32 had been involved in a recent food-poisoning episode, establishing the possibility that dangerous amounts would be used. The Secretary found the normal use data submitted in the

[5] A safe level of dosage to test animals would be an essential prerequisite to the establishment of a safe tolerance for man.

petitions to reopen to be inaccurate and incomplete, the pharmacological testing inadequate to establish the extent of toxicity to a certainty that would permit him to fix safe tolerances, and that there was no statutory authority on which he could issue regulations establishing tolerances for toxic coal-tar colors. He found also that the tests in the record are the tests customarily employed by competent toxicologists to determine the harmlessness of a substance, and that so far as is known no data exists which in any way contradicts the results of the studies shown in the record.

B. *Temporary Legislation:*

Before the administrative process had been completed, steps were taken in the Congress to enact legislation to keep Red 32 on the approved list for coloring oranges. After the tentative administrative order issued, a bill was introduced into the 84th Congress, H.R. 7732, to require the Secretary to continue the certification of Red 32 for coloring oranges until a color that is "more acceptable" (less toxic) should be "listed and made available for use." Hearings were held before the House Committee on Interstate and Foreign Commerce on February 10, 1956, a few days after the present cases were filed in the Court of Appeals for the Fifth Circuit. The Department of Health, Education, and Welfare opposed the bill. It proposed a temporary compromise to continue Red 32 on the list for coloring certain oranges for a period of not to exceed 3 years. This, it explained, was to allow time "for the development of a color that is not toxic," "for further exploration of the toxicity of FD&C Red 32", and "for further congressional consideration if a new color should not be found, and if it should be

necessary to amend the law to authorize the Department to prescribe a tolerance for Red 32 on oranges and impose other conditions to safeguard public health." In doing this, the Department explained that it had no positive proof that this temporary use would involve a likelihood of injury, but neither was there evidence available to establish that this use was wholly safe. The Department said that it could not agree to H.R. 7732, which would require the indefinite listing of Red 32 for oranges "before its safety for the purpose has been finally established" (Hearings, House Committee on Interstate and Foreign Commerce on H.R. 7732, 84th Cong., 2d Sess., pp. 2-3).

Both the House and Senate Committees adopted the Department's recommendations, but both made it clear that this temporary legislation was not intended to affect the outcome of the judicial review proceedings then under way in New York, Chicago, and New Orleans (*infra*, pp. 12-14). H. Rep. 1982, 84th Cong., 2d Sess., p. 3, and S. Rep. 2391, 84th Cong., 2d Sess., pp. 2-3.

The result of this Congressional consideration was Public Law 672, 84th Cong., 2d Sess., enacted July 9, 1956, 70 Stat. 512, under which the Florida and Texas orange growers were exempted from the prohibitions against Red 32 (now External D and C Red No. 14) until March 1, 1959.

Public Law 672 reads as follows:

> *Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,* That paragraph (c) of section 402 of the Federal Food, Drug, and Cosmetic Act, as amended, is amended by inserting immediately

before the period at the end thereof a colon and the following: "*Provided further*, That this paragraph shall not apply to oranges meeting minimum maturity standards established by or under the laws of the States in which the oranges were grown and not intended for processing (other than oranges designated by the trade as 'packing house elimination'), the skins of which have been colored at any time prior to March 1, 1959, with the coal-tar color certified prior to the enactment of this proviso as F.D. & C. Red 32, or certified after such enactment as External D. & C. Red 14 in accordance with section 21, Code of Federal Regulations, part 9: *And provided further*, That the preceding proviso shall have no further effect if prior to March 1, 1959, another coal-tar color suitable for coloring oranges is listed under section 406."[6]

C. *Litigation.*

1. The Certified Color Industry Committee sought judicial review of the Secretary's order in the Court of Appeals for the Second Circuit. On August 10, 1956, that court affirmed the order, 236 F. 2d 866.

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[6] There is pending in the 85th Congress H.R. 8945, a bill to authorize the Secretary to establish safe tolerances for coal-tar and other color additives. The Department of Health, Education, and Welfare reported on the bill on June 27, 1958, endorsing its principle, but asking for amendments which would provide clear authority and statutory guidance for limiting colors to particular foods and for fixing the maximum amounts of such colors as could be tolerated safely. The Secretary's report recognized that the present test of harmlessness is a stringent one, in the light of modern testing techniques, and asked the Congress for guidance as to changing the national policy with respect to tolerances for toxic coloring materials.

Eli Lilly thereupon dismissed its petition for judicial review in the Seventh Circuit.[8a]

The present cases were filed in the Fifth Circuit on February 2 and 8, 1956 (R. 2, 21) and were consolidated. On July 12, 1957, the Court of Appeals entered its judgment setting the order aside insofar as it removed Red 32 from the approved list of coal-tar colors that might be used on Texas and Florida oranges (R. 191-192). The court held that under existing law the Secretary had a duty to promulgate regulations establishing a safe tolerance and to continue the certification of Red 32 as a harmless coal-tar color for Texas and Florida oranges. This conclusion was reached by interpreting the word "harmless" in Section 406(b) as a relative term (R. 180-181, 183), and by reading Section 406(a) and 406(b) together to provide the needed statutory support for both a tolerance and the continued certification of Red 32 as a harmless coal-tar color for oranges.

The court said that Red 32 is an added poisonous substance (R. 182); that it is required in the production for market of oranges, because two Congressional Committees considering amendatory legislation found the practice of coloring oranges an economic necessity (R. 182); and that this usage is a safe one, because the Secretary (R. 180-181) and the Commissioner of Food and Drugs (R. 181, 186) have told the Congressional Committees that they know of no injury to man from color-added oranges. On this basis, the court reached its ultimate conclusion that "the 1939 finding should not be supplanted by a contrary ruling" "unless there is evidence that, in the amounts used, and in the man-

[8a] *Eli Lilly and Company* v. *Folsom, Secretary of Health, Education and Welfare* (C.A. 7, No. 11,682, January 16, 1957).

ner of use, oranges colored with Red 32 are unsafe for human consumption" (R. 186). While the Secretary is left free to make "further investigations" and to conduct hearings to decide whether he should or could promulgate a safe tolerance for Red 32 on oranges (R. 186-187), he is ordered to continue to certify the color as a safe one for this use on oranges without such a tolerance.

SUMMARY OF ARGUMENT

I

Under Sections 402(c) and 406(b) of the Federal Food, Drug, and Cosmetic Act (*supra*, pp. 3-4), Red 32—a toxic coal-tar—cannot be listed or certified as a harmless coal-tar color for use on any food in any amount.

A. The Secretary's undisputed findings, based on uncontroverted scientific investigations, establish that Red 32 is a toxic or poisonous coal-tar color.

B. The Act, which requires a certified coal-tar color to be "harmless," does not permit a toxic color such as Red 32 to be certified for any food use at all.

1. Congress used the word "harmless" in Section 406(b) without qualification to mean those coal-tar colors that have been demonstrated to be without adverse physiological effect and technically suitable for any use in food; in other words, colors that are wholly innocuous. The statute provides for the certification of the color as such, not for any particular use of the color on any particular article or in any particular amount. Either the color is safe for use without limitation or regulation, or it is unsafe and may not be used at all. There is nothing in Section 406(b) or Section 402(c) which suggests that the Secretary has a duty to

retain on the list of harmless colors any color that is toxic, but which might possibly be used in safe amounts on a particular product.

2. The Court of Appeals agreed that Red 32 is a poisonous and deleterious substance, but held that the Secretary had the duty to keep it on his harmless list and make it available to orange growers until he was prepared to prove that this single use of the color would make the oranges dangerous to the health of man. The court read into Section 406(b), dealing specifically with coal-tar colors, the provisions of Section 406(a), *supra*, p. 4, permitting the use of poisonous substances *required in production of food*, under tolerances established by the Secretary. But the structure of the Act indicates that Congress did not consider Section 406(b) to be qualified in any way by Section 406(a). The two provisions deal with separate aspects of the problem of poisonous materials and develop different methods of handling. No provision was made for fixing tolerances as to toxic coal-tar colors. They were completely prohibited.

3. The legislative history of the Act strongly confirms the consistent administrative interpretation that toxic coal-tar colors were to be prohibited completely, and were not to be certified for particular uses on particular products. Congress was fully aware of the difference between coal-tar colors and those poisons necessary in production of foods, and as to the former deliberately adopted an all-or-nothing attitude.

II

If Section 406(a) must be considered, despite our argument to the contrary in Point I, the court below misapplied it in expanding the statutory language "required in production" to include post-harvest treat-

ment of food to increase its acceptance in the market place by better coloration. "Required in production" means chemicals without which oranges cannot be brought to maturity, not post-harvest chemicals to promote salability. The expansive reading of the statute adopted below is contrary to the statute's basic aim to keep to an absolute minimum all poisonous and deleterious substances in our foods. Added poisonous and deleterious substances were banned without regard to whether the added substance might or might not render the treated food injurious. It was enough that the substance was a poisonous one. The only exception, for substances required in production or unavoidable, should be strictly construed to accomplish the evident purpose of the Act. A broad reading of the exception to cover poisons added for merchantability will open the national dietary to needless addition of poisons, and thus will have far-reaching consequences beyond the question of Red 32 for oranges. It will reverse national food policy which has been followed for years.

III

Even assuming the correctness of the statutory interpretations of the court below, the Court of Appeals was clearly in error in presuming the safety of Red 32 when used on oranges, rather than remanding the case to the Secretary for further proceedings, with the burden on the proponents of the tolerance to adduce proof that the color is required in production and that a safe tolerance can be established for it.

There is now no adequate factual evidence to establish a safe level of feeding Red 32 to test animals, and thus no basis at all for forecasting what would be a safe

level of feeding for man. Even if authorized by present law, a safe tolerance for Red 32 on oranges cannot be drawn on the facts now known.

The lack of definitive proof of past injury to man cannot be used as a basis for continuing the use of the color on oranges. The purpose of the statute is to require proof that the practice will be safe, not to require the Secretary to prove that it will be dangerous. The public, and not the food dyes, should be given the benefit of any doubt. The burden is on the makers and users of the toxic coal-tar, not on the Secretary.

ARGUMENT

The Fifth Circuit below, despite its acceptance of the Secretary's finding on uncontroverted evidence that Red 32 is a toxic substance, has held that he must continue to certify it indefinitely as a harmless color for use on Texas and Florida oranges. Under the decision, the Secretary cannot, as to oranges, now supplant the initial 1939 finding that the color is a harmless one until he is prepared affirmatively to prove that the color on oranges would render the oranges themselves injurious to the health of man and unsafe for human consumption. The court holds that a "harmless" color is one that is relatively harmless, not absolutely harmless, and that a color is harmless in a relative sense if there is no evidence that it may render this single food—oranges—injurious to health if used on oranges alone. This result the court obtains by reading into Sections 402(c) and 406(b) of the Federal Food, Drug, and Cosmetic Act, dealing specifically with coal-tar colors, the tolerance provisions of Section 406(a) which provide that the Secretary may permit the adding of a poisonous or deleterious substance to food "where such sub-

stance is required in the production thereof or cannot be avoided by good manufacturing practice". Then the court goes still further to construe "required in the production thereof", as used in Section 406(a), as meaning required *for marketing* by a substantial segment of the orange-producing industry. And finally the court undertakes for itself to decide that the coloring of oranges is safe and casts upon the Secretary the burden to show that safe tolerances cannot be established.

We submit that the decision below is erroneous in all three aspects. As to coal-tar products, Congress has not given the Secretary any authority to permit any use on any food product of those coal-tars which are found to be toxic—and the finding that Red 32 is toxic is undisputed. Congress has decreed that toxic colors are not to be used at all on any food. Hence, the Secretary has no power under the statute to fix tolerances for use of Red 32 for oranges. But even assuming that he does, the decision below has misinterpreted Section 406(a) in holding that "required in the production" means "required in the production *for market*" by a particular industry. Finally, the court erred in itself making the requisite finding that coloring of oranges was required for production. Tolerances safe for oranges alone might not be safe if other products can also show that they need the use of coal-tar colors for production or marketing. The burden of showing lack of danger from an admitted poison should not rest on the Secretary but on the industry.

I

Since Red 32 Is Poisonous, It Cannot, under the Federal Food, Drug, and Cosmetic Act, Be Listed or Certified as a Harmless Coal-Tar Color, or Used on Any Food in Any Amount

A. *The undisputed evidence establishes that Red 32 is a poison when ingested internally and cannot be classified as harmless.*

The court below held that there was adequate support for the Secretary's finding that Red 32 is a toxic color. There can be no doubt, on this record, as the Second Circuit has also held,[1] that the coloring materials as such are chemicals with demonstrated acute and chronic toxicity which may be used at levels which jeopardize the public health.

Findings 7-9 (R. 163-164), based on unchallenged scientific studies, detail the injuries to test animals clearly attributable to dye feeding. See the Statement, *supra*, pp. 6-8. While man cannot ordinarily be used as a test animal, the adverse effects produced in the laboratory on rats, dogs, and mice furnish material for assaying the toxic potential of color to be fed to man in his diet over a protracted period. Cf. *United States* v. *Wood*, 226 F. 2d 924, 927 (C.A. 4) and *United States* v. *Lesser*, 66 F. 2d 612 (C.A. 2). The only difference in response between man and test animals shown on this record is that, judged by the observable symptoms, man is somewhat more sensitive to Orange 1, the least toxic of the three colors involved in the administrative proceeding, than either the rat or the dog. And it is an accepted principle of the science of pharmacology that,

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[1] *Certified Color Industry Committee* v. *Secretary*, 236 F. 2d 866.

on the basis of equal body weights, most animals are from five to ten times more resistant to a toxic agent than is man. *Procedures for the Appraisal of the Toxicity of Chemicals in Foods, Drugs, and Cosmetics*, 10 Food Drug Cosmetic Law Journal 679, 748 (Oct. 1955).

In considering the significance of the laboratory experiments, the expert agency had the practical problem of forecasting from the observed injuries to animals whether the colors would be deleterious to man. This was not too difficult, because adverse effects were produced by the lowest levels fed to both animal species tested, and, fortuitously, evidence as to man's response came from a poisoning episode with obvious symptoms —vomiting and diarrhea. Experience in the candy episode (R. 161, 163-164, Findings 4 and 9) and in the more recent popcorn poisoning (R. 155) has shown that Orange 1 and Red 32 can cause and have caused acute human poisoning.

B. *The statute, read as a whole and in the light of its history, excludes toxic coal-tar colors from listing and certification for any food use at all.*

As we read the statute, the undisputed factual finding that Red 32, a coal-tar color, is a substance dangerous to man—*i.e.*, it is *not* harmless—disposes of the issue in this case. Except for the special legislation permitting its use on oranges until March 1959 (*supra*, pp. 10-12), we believe that Congress has decreed that coal-tar colors which are not generally harmless and safe for unlimited use are not to be used in food at all.

1. The terms of Sections 402(c) and 406(b) require certified coal-tar colors to be wholly harmless.

The delegation to the Secretary by Section 406(b) of the Act (*supra*, p. 4) is plain and direct in its terms. He is told to——

> * * * promulgate regulations providing for the listing of coal-tar colors which are harmless and suitable for use in food and for the certification of batches of such colors, with or without harmless diluents.

Similarly, Section 402(c) (*supra*, p. 3) provides in absolute terms that a food shall be deemed adulterated "If it bears or contains a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by section 406."

This language embodies an all-or-nothing attitude toward coal-tar colors. Under the statutory scheme, the Secretary is directed to list and certify batches of harmless coal-tar colors suitable for use in foods, drugs, and cosmetics. If a color is from a certified batch, *any* food containing it is not adulterated; if the color is from an uncertified batch, *any* food containing it is adulterated. In other words, the coloring is either generally safe for use without limitation or it cannot be used at all.

The coal-tar color must be "harmless" before it can be certified. "Harmless" is a well-understood word which means "free from harm or the power to harm." [8]

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[8] The following definitions appear in standard dictionaries:

Webster's New Collegiate Dictionary, page 376:

"harmless—(1) Free from harm, liability, or loss. (2)

"Harmless", when unqualified, does not mean relatively free from harm, or only moderately harmful, or non-injurious for certain uses. It means "innocuous". There is no qualification in the statute which justifies the court below in reading "harmless" as "relatively harmless" in relation to a particular use on a particular product. Nor is any provision made for individual certification for a particular use or a particular product or for particular amounts.

Had Congress intended any qualification on the word "harmless," the language was readily at hand. Yet it made no qualification. Authority for so reading "harmless" was found by the court below in *United States* v. *Lexington Mill & Elevator Co.*, 232 U.S. 399, and *W. B. Wood Mfg. Co.* v. *United States*, 286 Fed.

Free from power to harm; inoffensive; innocuous."

Webster's New International Dictionary, page 1139:

"harmless—(1) Free from harm; unhurt; free from liability or loss; as a bond to save one harmless. (2) Free from power or disposition to harm; inoffensive."

Funk & Wagnalls New Standard Dictionary, page 1117:

"harmless—(1) Having no power, tendency, or inclination to injure; innoxious; as, a harmless scheme; a harmless drug. (2) Without hurt, loss, or liability; uninjured; as, to escape harmless; to give bond to save another harmless."

The New Century Dictionary, page 715:

"harmless—Free from harm, unharmed, or uninjured (now rare); free from liabilty or loss (as to hold or save one harmless, as by the terms of an agreement); also, having done no harm, or innocent (archaic); now, commonly, destitute of power or tendency to harm; innocuous; inoffensive."

84 (C.A. 7) (R. 180). But "harmless" was not a part of the statute involved in those cases; rather, the statutory language was that food would be regarded as adulterated if it bears or contains an "added poisonous or other added deleterious ingredient which may render such article [food] *injurious to health.*" (Emphasis added.) Moreover, Congress added the new provisions of Section 406(b) to the Act when it was revised comprehensively in 1938 with the very purpose of overcoming the effect of the *Wood* decision (see *infra,* pp. 30 *et seq.*).

It is significant that the statute provides for certification of the color, as such, not for any particular use of the color, and without reference to amounts. Certification means to attest authoritatively—in this case, to declare officially that each production batch of Red 32 is a harmless coal-tar color. Certification to this fact is made on the basis of the examination of samples of the color in the laboratories of the Food and Drug Administration. 21 C.F.R. Part 9. Once the Secretary's stamp of approval is put on a batch of color, any manufacturer using the certified color in his food, drug, or cosmetic is officially assured of the color's harmlessness. He may use the color to achieve any tinctorial hue he desires and in any amount. Certification after careful laboratory analysis of a batch of color would be a pointless procedure if the product certified as harmless is instead an active poison which can cause harm if ingested in sufficient quantities. Such certification would do little or nothing to protect the public health, and might indeed have the opposite effect. Congress adopted the certification plan to make it unnecessary to examine colored foods to assure safety. It took no chances, and excluded from foods

all but certified harmless colors. This enables the Department of Health, Education, and Welfare to protect the public from unsafe coloring matter in food by simply refusing to certify any color that is not itself wholly harmless.[9]

2. *Section 406(a), with its provision for tolerances, is inapplicable to coal-tar colors.*

As support for its holding that the statute permits the particular use of a coal-tar color which cannot be certified as wholly harmless, the court below turned to Section 406(a), *supra*, p. 4, which deals with a different subject (added poisonous and added deleterious substances required in the production of food) and provides a different system of control (the enforcement of tolerances established by regulations, not the certification of batches of coal-tar color). But Section 406 (a) is inapplicable to coal-tar colors.

In Section 406(a), Congress recognized that there may be instances in which poisonous or deleterious ingredients should be permitted in food. It enacted a single exception to the flat prohibition against added poisons in food. That exception applied only to substances "required in the production thereof or [which] cannot be avoided by good manufacturing practice." And the Congress directed the Secretary (1) to establish tolerances for such required or unavoidable substances, limiting the quantity therein or thereon to such extent as necessary to protect the public health; (2) to "take into account the extent to which the use of such sub-

[9] Plainly, the color industry has so understood the plan of control. It has treated the colors, once certified, as wholly innocuous, and by the admission of the industry committee spokesman at the hearing has made no effort to learn how much color was being used in a variety of foods (R. 228).

stance is required or cannot be avoided in the production of each" article on which the poison is tolerated; and (3) to consider "the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances."

Yet in the very next paragraph—Section 406(b)—Congress authorized the promulgation of regulations to provide for listing and certification of "harmless" coal-tar colors. Plainly, the language was neither inadvertent nor meaningless. A coal-tar color could not be at once a poisonous substance controlled by paragraph (a) and a harmless color controlled by paragraph (b). Congress excluded poisonous color-tar colors from paragraph (a) altogether, and pointedly said not a word in paragraph (b) about tolerances for coal-tar colors as a means of transposing a toxic substance into a "harmless" one. The two paragraphs were arranged to deal with two related, but different, subjects. While tolerances were authorized by Section 406(a) for added poisonous and deleterious substances required in production or unavoidable in good manufacturing practice, Section 406(b), immediately following and relating specifically and solely to coal-tar colors, uses the unqualified words "harmless and suitable for use in food." It says nothing at all about tolerances.

Congress must have recognized that coal-tar colors —which are manufactured to be added to foods, drugs and cosmetics for eye appeal alone—are not *required* in the production of such articles and can be avoided. It, therefore, provided for a list of harmless coal-tar colors that could be used without proof of necessity. To provide for tolerances for toxic coal-tar colors would run counter to the basic spirit of the Act, so strongly expressed in Section 406(a), to prevent the

use of poisons in food except where absolutely necessary or carefully controlled.

It seems clear that the Secretary was quite correct when he said in this case (R. 156):

> No standard or criteria have been established by the Congress whereby the Secretary may tolerate small amounts of poisonous colors in food, drugs or cosmetics.* * *
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> * * * the Federal Food, Drug, and Cosmetic Act does not establish a standard or guide by which the Secretary could select some products, and exclude others, in allowing use of small amounts of coal-tar colors which are toxic. The only method by which such a result could be reached would be arbitrarily to state that the color or colors would be limited to some foods, drugs, or cosmetics and not to others.

The Secretary could not borrow the criteria from Section 406(a), because toxic colors are neither required in production nor unavoidable in good manufacturing practice. And he dared not embark on a tolerance program without statutory guide lines, for to do so would open the Nation's food supply to unnecessary and avoidable poisons in defiance of the flat prohibitions of both Section 406(a) and (b). Perhaps tolerances should be established for coloring, under adequate guides, as the Secretary has agreed with respect to pending legislation (see the Statement, *supra*, p. 12, fn. 6). But that is for Congress to decide. Under the statute as it now stands, no such provision is made. The Secretary is merely directed to certify colors as wholly harmless; he is not given authority to certify them for use in particular quantities as to particular

foods. Up until now, the Congressional attitude has been that, if coal-tar colors are not wholly safe, they shall not be used in food at all. And this is a very significant choice of policy; under the present statute, which has no guidelines, if a color must be certified as not harmless in a particular use, such as oranges, it would presumably also have to be certified as not harmless in other particular uses, such as margarine. Even if each separate use alone would be safe, the total amount of color added to the totality of foods could well result in injury to health. Congress has thus far avoided that possibility by a flat prohibition on the use of toxic coal-tar colors.

3. *The legislative history and background of the statute show that Congress intended to prohibit listing or certification of toxic coal-tar colors for any purpose or use.*

Prior to 1938, Congress dealt with "added poisonous and other added deleterious substances in food", but not specifically with coal-tar colors. Section 7 of the original Pure Food and Drugs Act provided (34 Stat. 769) that food shall be deemed adulterated——

> If it contain any added poisonous or other added deleterious ingredient which may render such article injurious to health * * *.

This Court in *United States* v. *Lexington Mill and Elevator Co.*, 232 U.S. 399, 411, construed that section to give it comprehensive meaning. The Court said:

> It is not required that the article of food containing added poisonous or other added deleterious ingredients must affect the public health, and it is not

incumbent upon the Government in order to make out a case to establish that fact. The act has placed upon the Government the burden of establishing * * * that the added poisonous or deleterious substances must be such as may render such article injurious to health. The word "may" is here used in its ordinary and usual signification. * * * In thus describing the offense Congress doubtless took into consideration that flour may be used in many ways, in bread, cake, gravy, broth, etc. It may be consumed, when prepared as a food, by the strong and the weak, the old and the young, the well and the sick; and it is intended that if any flour, because of any added poisonous or other deleterious ingredient, may possibly injure the health of any of these, it shall come within the ban of the statute. If it cannot by any possibility, when the facts are reasonably considered, injure the health of any consumer, such flour, though having a small addition of poisonous or deleterious ingredients, may not be condemned under the act. This is the plain meaning of the words * * *.

In accord with this broad scope of the law, the administrators of the Act early initiated a voluntary system of certification for coal-tar colors. This system was the product of one of the most comprehensive investigations ever undertaken by the old Bureau of Chemistry, then charged with administration of the food and drug law. The Department of Agriculture employed an outside expert on coal-tar colors, Dr. Berhard C. Hesse, to develop the system. Dr. Hesse's monumental work, Bureau of Chemistry Bulletin No. 147, was issued in February 1912. In transmitting it to

the Secretary of Agriculture, Dr. Harvey W. Wiley stated that the data developed by Dr. Hesse formed the basis for Food Inspection Decisions 76, 77 and 106. Much of the Bulletin was devoted to the "harmfulness of coal-tar colors and their physiological effects." After reviewing all the existing scientific literature, the laws of foreign countries, the recommendations of producers and users of coal-tar colors, the Bulletin recommended that only 7 colors be permitted in foods. The rules governing the selection of the colors were (pp. 161-162 of the Bulletin):

Rule I. All colors which have not been physiologically tested either upon animals or man shall not be permitted for use in foods.

Rule II. All coal-tar colors which have been examined physiologically with contradictory results shall not be permitted for use in foods.

Rule III. All coal-tar colors which have been examined physiologically and have been declared to be of doubtful harmlessness shall not be permitted for use in foods.

Rule IV. Only those coal-tar colors whose chemical composition was definitely disclosed or otherwise ascertained . . . and which have been examined physiologically and with no other than a favorable result shall, for the present, be permitted for use in foods.

These rules were evolved after a public hearing in New York City (Bulletin, pp. 47-51), at which several persons recommended that colors be allowed in food if

"harmless in the quantities employed." Calvery, *Coal-Tar Colors, Their Use in Food, Drugs, and Cosmetics,* 114 American Journal of Pharmacy, 326 (1942). But that idea was rejected, in favor of the position advocated by others who participated in the hearing—that the rules should permit only the colors "which have been proven to be entirely harmless, even if taken in large doses" (Bulletin, 51, 61-62).

Though it continued to employ this voluntary system, the Government found it virtually impossible to proceed in court against poisonous coal-tar colors in foods, primarily because of the difficulty of proving that the particular amount of the toxic color in the particular food "may render [the food] injurious to health." *W. B. Wood Manufacturing Co.* v. *United States,* 286 Fed. 84, 86 (C.A. 7), held that such proof was necessary.

Accordingly the Department of Agriculture recommended that Congress make the certification system mandatory and reverse the effect of the *Wood* case by describing as adulterated foods those bearing uncertified coal-tar colors.

Senator Copeland's memorandum on S. 1944, 73rd Cong.,[10] discussing the weaknesses of the original 1906 Pure Food and Drugs Act,[10a] pointed out that that law had no provision prohibiting use of uncertified coal-tar colors in food, and that:

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[10] Dunn, *Federal Food, Drug, and Cosmetic Act,* a Statement of its Legislative Record, pp. 30-31. This was the original bill which culminated in the 1938 revision. Senator Copeland, a medical doctor who had been a public health official of New York State, was the leading sponsor of the legislation throughout its entire 5 year course in Congress.

[10a] 34 Stat. 768, c. 3915, Sections 1-11.

> * * * No action can be taken unless it can be proved that colors or their impurities are poisonous and that they are present in such quantities as may be harmful to health.

The purpose of the amendment providing for listing and certification of harmless coal-tar colors, he said, was to overcome the need which arose under the 1906 Act to prove that the colors or impurities were "present in such quantities as may be harmful to health." The voluntary system of certification was expressly called to the attention of the Congress. Describing it, the Senate Committee said (S. Rep. 361, 74th Cong., 1st Sess., 6-8 (1935); Dunn, *op. cit.*, p. 243):

> As a matter of administrative practice in the Department of Agriculture, provision was made for the certification of coal-tar colors shortly after the enactment of the present law. Under this procedure those colors which were demonstrated to be without adverse physiological action, and which from a technical standpoint were suitable for use as food colors, were admitted for certification. Individual batches of these particular colors were then certified by the Department after examination which demonstrated their freedom from toxic impurities. This has resulted in an adequate supply of harmless colors for all food uses and has operated to the satisfaction of the industry. Nevertheless, uncertified colors such as paint pigments, many of which are distinctly harmful, have been used from time to time. * * * * * legislative sanction

> is given to the administrative practice of the Department in certifying colors.[11]

This explanation was drawn almost verbatim from the testimony of Walter G. Campbell, then Chief of the Food and Drug Administration. See Hearings before the Senate Committee on Commerce on S. 2800, 73d Cong., 2d Sess., p. 597; Dunn, *op. cit.*, pp. 1201-1202; and Hearings Before the Senate Committee on Commerce on S. 1944, 73d Cong., 1st Sess., p. 28.

Congress thus accepted the idea put forward by Mr. Campbell that the certification regulations should assure manufacturers and other purchasers "that the colors used by them would be nontoxic and free from deleterious ingredients." As the Senate Report already quoted (*supra*, pp. 31-32) put it (S. Rep. 361, 74th Cong., 1st Sess., p. 7; Dunn, *op. cit.*, p. 243):

> Paragraph (c), prohibiting the use of any coal-tar color other than a certified color, is a precaution against the promiscuous use of coal-tar colors, the number of which is legion, and the most of which are toxic.

With respect to the present claim that tolerances can be established for these toxic coal-tar colors, it is significant that, throughout the legislative history, the provisions as to coal-tar colors are discussed separately from those with respect to tolerances. For example, in S. Rep. 361, 74th Cong. 1st Sess. 6-8, Dunn, *op. cit.* pp. 241-243, the Committee first discussed the ban on poisons with provision for tolerances and then discussed

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[11] These same ideas were expressed in reports on other bills, out of which finally came the Federal Food, Drug, and Cosmetic Act. S. Rep. 493, 73d Cong., 2d Sess., pp. 4-6, Dunn, *op. cit.*, at 113-114 (on S. 2800); H. Rep. 2139, 75th Cong., 3d Sess., p. 6, Dunn, *op. cit.*, at 820.

the provision against "the use of any coal-tar color other than a certified color." And it is also indicative of the Congressional understanding that such tolerances could *not* be fixed for coal-tar colors on particular foods. An attempt was at one time made to make special provision for the coloring of oranges. At one point early in the legislative development of the Federal Food, Drug, and Cosmetic Act, a provision was inserted in S. 2800 to guarantee the continued availability of coloring for citrus fruit. This proviso said:

> Sec. 3(e). Nothing in this Act shall be construed to prohibit the enhancement of the color of mature and wholesome citrus fruits to the varietal color thereof, by means harmless to the consumer of such fruits, nor to require any declaration of such enhancement, by labeling or otherwise.

S. 2800, 73d Cong., as amended by the Senate Committee on Commerce, 78 Cong. Rec. 4567; Dunn, *op. cit.*, at pp. 167, 169. That proviso would have been unnecessary if Congress had contemplated the fixing of tolerances for coal-tar colors under the equivalent of present Section 406(a). But while Section 406(a) appears in substance in all the subsequent bills, the proviso as to oranges did not reappear in the bills either in the 74th Congress or the 75th Congress, S. 5, 74th Cong., Dunn, *op. cit.*, at pp. 213, 216, 513, 533: and S. 5, 75th Cong., Dunn, *op. cit.*, pp. 633, 644. In its stead, a proviso emerged in the bill reported by the House Committee (Dunn, *op. cit.*, pp. 774, 800) which simply protected the citrus growers in the use of existing colors until applications for their listing as "harmless" colors could be acted on by the Department.

This legislative episode shows that Section 406(a), dealing with tolerances for necessary poisons, and Section 406(b), dealing specifically with coal-tar coloring, were considered as covering separate aspects of the problem of keeping food healthful. It did not appear to be the view of anyone, not even those anxious to preserve coloring for oranges, that coloring matter could be covered by the tolerance procedure authorized in Section 406(a) for poisons necessary for production of foods.

We believe that this legislative history strongly confirms the Secretary's understanding of Section 406(b), *supra*, p. 4, which allows the listing and certification only of colors demonstrated to be without adverse physiological effect. Under this construction, colors which may readily be used in amounts that would injure man cannot be certified as harmless.[12] As we have shown,

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[12] At one point in the opinion below, the court said there was no need to pursue the inquiry whether there had been an administrative construction contrary to the one urged here (R. 177). Later, however, the court said that the Secretary at one time seemed to be of the opinion that he had the power to establish a tolerance for toxic colors and had done so with respect to certain "lakes" used on Easter eggs (R. 183-184). There is no record explanation of why the lakes were so restricted. The record in the hearing in 1939, on which the regulation was based, shows that toxicity of the lakes was not even involved. In fact, this restriction was made because the lakes produced "mottled shades of green, yellow, red [and] blue", so desirable on Easter eggs but wholly unacceptable in coloring other foods. Record, 1939 Hearing for * * * Amending Regulations under the Federal Food, Drug, and Cosmetic Act for the Listing of Coal-Tar Colors, F.D.C. Docket 13, p. 40. The required label statement was to avoid consumer disappointment with the color, not to allow the sale of toxic dyes. Moreover, the Annual Report of the Food and Drug Administration for 1934, p. 6, contained the following discussion of coal-tar dyes used on Easter eggs:

"Another brief campaign of probable, public-health significance was undertaken just before Easter and resulted in removal from

there is not a hint of a suggestion that Congress intended the listing of toxic colors with tolerances to restrict the amounts of such colors that might be safely used in particular foods. Nothing could be clearer than that Congress did not intend, by the new language of Section 406(b) and 402(c), to accomplish only what had been the law under the original 1906 Act, as construed in the *Wood case, supra,* pp. 22, 30. Cf. *United States* v. *Walsh,* 331 U.S. 432, 436-437. The purpose of Congress was to make the former voluntary system mandatory, and to require the Department to list and certify only innocuous coal-tar colors, which could then be used by all food, drug, and cosmetic manufacturers without restraint as to quantity or commodity to achieve any desired tinctorial hue.[13]

II

Even If the Standards of Section 406(a) of the Federal Food, Drug, and Cosmetic Act Are Applicable to Coal-Tar Colors, There Is No Proof That Coal-Tar Coloring Is Necessary for the Production of Oranges Within the Meaning of That Section

As discussed above, pp. 19-35, we believe it was error to construe Section 406(a) as having any applicability at all to coal-tar colors. However, even if appli-

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the market of 16 consignments of Easter-egg dyes containing poisonous ingredients. The colors seized were essentially in the class of house paints, containing such toxic ingredients as cadmium sulphide, zinc sulphide, and barium sulphate with small percentages of lead as a contaminating impurity. Most egg dyes are harmless, and there is every reason to believe that these actions have put a stop to the distribution of poisonous products of this class."

This plainly shows that the Administration has been consistent in its insistence that coal-tar colors be harmless, regardless of the use.

[13] It goes without saying that the construction of Section 406(b) adopted by the court below goes contrary to the established administrative understanding and practice. See footnote 12, *supra*. *E.g.*, *United States* v. *Allen-Bradley Co.*, 352 U.S. 306, 309.

cable, the section has been misapplied by the court below by equating "required in the production" with economic needs in merchantability, and by authorizing continued use of the color before the Secretary has taken the necessary steps to establish the tolerance.

A. *Section 406(a) was designed as a narrow exception to a flat prohibition against the use of poisons in food.*

The general philosophy of the Act, as it deals with poisonous substances, is apparent from Sections 402(a) and 406(a) *supra,* pp. 3-4. Section 402(a)(1) provides that a food shall not be deemed adulterated "If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an *added* substance such food shall not be considered adulterated * * * if the quantity of such substance in such food does not *ordinarily* render it injurious to health * * *." [Emphasis added.] Section 402(a)(2) provides that a food shall be deemed adulterated "if it bears or contains any *added* poisonous or deleterious substance which is unsafe within the meaning of section 406." [Emphasis added.] And section 406 declares all added poisonous or deleterious substances unsafe, unless required in production or unavoidable in good manufacturing practice. Section 406 then allows the Secretary to promulgate tolerances as to quantities of such *added* poisonous or deleterious substances when they can be safely permitted in a variety of foods.

Thus, even in regard to those poisonous substances which were not singled out for special treatment, as were coal-tar colors, the Act authorizes tolerances only where such substances are necessary or unavoidable.

The only poisonous substances allowed in food at levels which do not "ordinarily" render the food injurious to health are those which are not added, but are normally present as natural components of food, such as oxalic acid in spinach. The test applicable to naturally occurring poisonous substances was rejected both for added poisons and for "harmless" coal-tar colors. Rather, Congress established a strict general rule of exclusion against all poisonous and deleterious substances that might be added to foods. This was without regard to whether the added substances might or might not render the treated food injurious to health. It was enough that the added substance itself was a poisonous or deleterious one.

A single exception was made. When the added substance was required in the production of food or could not be avoided by good manufacturing practice, the Secretary was authorized to establish a tolerance for it, taking into account the extent to which the added substance was required or was unavoidable, the amount of the poison that might be safely tolerated, the extent to which the poison was required or unavoidable in this and other foods, and the other ways in which the consumer might be affected by the same or other poisonous or deleterious substances.

This was a new legislative approach to added poisons. As noted *supra*, pp. 27-28, this Court, in *United States* v. *Lexington Mill & Elevator Co.*, 232 U.S. 399, 409-411, had held that under the 1906 language a food was adulterated if it contained any added poisonous or deleterious ingredient which may possibly injure the health of any consumer, "the strong and the weak, the old and the young, the well and the sick." If the added substance in the food could not "by any possibility" injure the

health of any consumer, the small addition of poisonous or deleterious ingredients was not condemned. As strong as this prohibition was, it did not go far enough. Each food had to be considered alone, and there was no adulteration unless the particular food contained enough poison so that that food "may" be injurious to health. Small amounts of the same poison in a variety of common foods in the diet were beyond effective control.

The new provision in Section 406(a) was designed to arm the Department with power to establish tolerances for the entire variety of foods in which a common poison or related poisons were required or were unavoidable, and thereby to limit man's total intake of each such poison to a safe level.

This provision was advocated by Mr. Campbell for the Food and Drug Administration. He said, in discussing this provision of S. 2800, 73rd Congress, 2nd Sess.:

> ". . . Control of added poisons in food and cosmetics is one of the most important provisions of the bill. It is impossible to eliminate entirely all added poisonous substances, but it is important that the amount the consumer ingests be kept to such a low limit that his total intake of the poisons will not impair his health. This can be done only by placing definite limitations on added poisons where they are unavoidable, as in the case of fruits and vegetables where spraying is essential to their production, and by prohibiting entirely the addition of poisons to foods where it is practicable to do this and where the added poison serves no genuinely useful purpose. In the present law it is necessary in a proceeding based on added poison to

show that the food in the particular shipment on which the proceeding is based contains added poison in such quantity as may impair the consumer's health. No account can be taken in such proceedings of the probable intake of the same or similar poisons from other sources. * * *

* * * * *

* * * In promulgating such tolerances this section requires that there be taken into account the extent to which the use of the poison is required in the production of the article and the other ways in which the consumer may be affected by the same or other poisonous substances. This will permit the establishment of comparatively liberal tolerances for any food where poison is unavoidable or is required by the necessity of production, and less liberal tolerances or complete prohibitions where it is practicable to limit the amount or to eliminate the poison completely. Such entire prohibition would be justified in those situations where irresponsible manufacturers, for some fanciful or real commercial advantage, add dangerously toxic substances to food as, for example, the addition of ethylene glycol to frozen eggs to promote "smoothness", or maleic acid to fats and oils to prevent rancidity when preservation can be accomplished by observance of sanitary conditions and by the use of refrigeration. In approaching the problem of control from this angle, the amount of added poisons can be so allocated to different foods, in accordance with the practical necessities, that on the basis of the probable consumption of various foods consumers will not receive an aggregate

quantity of poisons sufficient to jeopardize health.

* * * * *

Hearings before the Senate Committee on Commerce, on S. 2800, 73d Cong., 2d Sess., pp. 596-597; Dunn, *op. cit.*, p. 1201.

Congress adopted this policy. It explained Section 406(a) [then Section 304(a) of S. 5, 74th Cong.] as follows:

> [This] prohibits the addition of poisonous or deleterious substances to food except where such addition is required in production, as in the case of poisonous sprays for fruits and vegetables to protect them against insects or fungus diseases, or where such addition cannot be avoided in good manufacturing practice, as where purification processes cannot entirely eliminate a contaminant of raw materials, or where some contaminant is unavoidably introduced in factory operations. This section then authorizes the establishment of tolerances for the protection of public health in those instances where the addition of the poison is required or cannot be avoided.* * *

S. Rep. 361, 74th Cong., 1st Sess., pp. 6-8; Dunn, *op. cit.*, pp. 241-242. See also S. Rep. 493, 73d Cong., 2d Sess., pp. 4-6; Dunn, *op. cit.*, p. 113.[14]

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[14] S. Rep. 493 states:

> "* * * In promulgating such regulations this section requires that there be taken into account the extent to which the use of the poison is required in the production of the article, as for example, poisonous sprays in producing certain fruits and vegetables, and likewise, the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances. This authorization will permit the establishment of comparatively liberal tolerances for any food where poison is unavoidable or is required by the necessities

In short, the basic attitude of Congress toward poisonous materials, as reflected in Section 406(a), is that they should not be added to food at all. The exception for tolerances to be fixed by the Secretary was intended to be limited to situations of real necessity—when the substance is "required in the production thereof or cannot be avoided by good manufacturing practice."

B. *There is no record basis for a finding that Red 32 is "required in the production of" oranges.*

Considering the very narrow scope of the exception created by Congress in Section 406(a), it is inconsistent with its purpose to construe the section's words "required in the production", as the court below has construed them, as meaning "required for marketability."

The hearing before the Secretary was not at all concerned with the question whether Red 32 is "required in the production" of oranges.[15] Indeed, the Florida

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of production, and less liberal tolerances or complete prohibitions where it is practicable to limit the amount of poison in a particular food to very small quantities, or to eliminate it completely. It will likewise afford adequate control of those situations where irresponsible manufacturers, for some fancied or real commercial advantage, add dangerously toxic substances to foods, as, for example, the addition of maleic acid to fats and oils to prevent rancidity when preservation can be accomplished by observance of sanitary conditions in manufacture and packaging and by use of refrigeration for the finished product.

"In approaching the problem of control from this angle the amount of added poisons can be so allocated to different foods, in accordance with the practical necessities, that on the basis of the probable consumption of the various foods consumers will not receive an aggregate quantity of poisons sufficient to jeopardize health. * * *"

[15] The Secretary's order should stand or fall on whether he fairly dealt with the whole issue before him, *i.e.*, the harmlessness of

Citrus Commission's witness said that the Commission did not oppose any action the Secretary might deem advisable on the basis of the record (R. 224). And the motions to reopen did not offer any proof on the point. Respondent Schell wanted to prove that there was a sinister motive behind the proceeding (R. 117-118), and that no possible harm could come from the consumption of color-added oranges (R. 118-119). The Color Industry motion offered to prove that under "normal conditions of use" the three colors would be classified as harmless (R. 152-153). The idea of tolerances under Section 406(a) was mentioned only briefly in respondent Schell's brief (R. 138), but was not pressed until the case reached the Court of Appeals.

There, after holding that Section 406(a) should apply, the court found that Red 32 had been described as an economic necessity by two Congressional Committees, and thus that it is "required in the production for market of oranges grown by a substantial segment of the orange producing industry" (R. 175, 182-183). It held also that the Secretary need not consider other uses of Red 32, since even though there was no express provision permitting him to do so, neither was there a prohibition in the statute against his limiting the color to this single use (R. 183).[16]

Red 32 when listed for unrestricted use in foods, drugs, and cosmetics. The court below agreed with his handling of this broad question, but said he could not take Red 32 away from the orange growers. A rule of general applicability should not be set aside simply because it works a hardship on some who are affected by it. In *Federal Security Administrator* v. *Quaker Oats Co.*, 318 U.S. 218, a wholesome product with a commercial history had to be withdrawn from the market because the regulations fairly established standards for related foods.

[16] While the court limited its judgment to Red 32 on mature oranges, it said: "If there be other like situations, then of course that which we hold will be applicable to them" (R. 179).

"Required in production" of oranges, we believe, means substances required in growing the fruit, not post-harvest treatment of the food to promote its attractiveness in the market place. In the first place, this is what Mr. Campbell and the Congressional Committees thought the phrase meant. *Supra*, pp. 38-41.[17] Second, "production" does not normally include marketing. Third, "required", in the context of this statute (cf. *Armour & Co.* v. *Wantock*, 323 U. S. 126, 129-130), is not to be given an expansive meaning so as to include poisons in the food supply. Rather, it should limit the number to those poisons which can meet the rigid standards established by Congress. It must be read narrowly as part of an exception to the general rule of blanket exclusion of poisons, and not to cover toxic substances which might be added for some "fancied or real commercial advantage."

Should this court sustain the holding below, it would, of course, have far reaching significance beyond Red 32 as used on oranges. Such an interpretation would apply not to oranges alone, but to all foods in which a toxic substance might contribute something to salability. It would reverse a long standing Departmental policy which has excluded from foods such substances as poisonous artificial sweeteners, 21 C. F. R. 3.14, coumarin, 21 C.F.R. 3.33, and quarternary ammonium compounds, 21 C.F.R., 1958 Cum. Supp., 3.203. In May 1957, the Department published an order removing yellow colors, used principally in margarine, from the list of colors available for unrestricted use in

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[17] H.R. Rep. 2139, 75th Cong., 3d Sess., p. 6, Dunn, *op. cit.*, 815, 820, said: "It is well recognized that an adequate fruit and vegetable supply could not be brought to maturity without the use of toxic insecticides and fungicides."

food, drugs, and cosmetics, 22 F.R. 3173. Coloring is probably as important a factor in the marketing of margarine as it is in the marketing of oranges. If, despite our argument in Point I, tolerances are to be applied to coal-tar colors, and the test of necessity for such a tolerance is to be the use of the color in promoting marketability, it is obvious that much more than oranges will be affected by the decision below.

But the basic fact is, as we have shown, that the test of marketability has not been established by Congress. Congress has decided as a temporary measure that, until March 1959, coloring may be used on oranges alone. *Supra*, pp. 11-12. If Congress desires to continue that exception, it can do so. But a rule laid down by this Court in favor of respondents would be a general interpretation which could affect, beyond 1959, not only coal-tar colors, but the standards to be applied to determining whether tolerances should be allowed under Section 406(a) as to all kinds of poisonous substances. Such an interpretation would be clearly incompatible with the statutory language of Section 406(a)—"required in the production thereof"—even if that section is to be applied to coal-tar coloring.

III

The Court Below Was Not Justified in Making Its Own Finding That Coloring for Oranges Is Required for Production and Casting on the Secretary the Burden to Show That Safe Tolerances Cannot Be Established

Section 406(a) provides for the use of a dangerous substance in food in accordance with tolerances fixed by the Secretary after consideration, not only of the necessity for its use "in the production of" a particular food, but also of the degree of danger represented by the use of similar substances in other foods. Hence,

even assuming the correctness of the statutory interpretations by the court below, it erred in itself making the requisite finding that coloring of oranges was required for production (including marketing) and casting the burden on the Secretary to show that safe tolerances cannot be established. As pointed out above, at pp. 26-27, 39-40, 43-44, tolerances safe for oranges alone might not be safe if, under the interpretation of the court below, other products can also show that they should be allowed to use coal-tar colors because required in their production or marketing. On this record, the court below was not justified in presuming that proper tolerances could be established.

A. *The facts needed to establish a safe tolerance for Red 32 on oranges do not exist.*

Actually, there is on this record no proof that the use of Red 32 on oranges alone is safe, much less proof that safe tolerances for general use can be established. The sole support for the view that the use of Red 32 on oranges is safe comes from outside the record—from statements made by the Department of Health, Education and Welfare in commenting on the temporary legislation (legislation the opinion below renders unnecessary).[18] The court below takes the Secretary's "guarded statement"—that on the evidence so far available there has been no established likelihood of injury to man from eating color-added oranges—as an apparent concession that Red 32 on oranges would involve no hazard to health (R. 180). The safety of the

[18] Hearings before a Subcommittee of the House Committee on Interstate and Foreign Commerce on H.R. 7732, 84th Cong., 2d Sess., pp. 2-3, 17-18.

practice is taken as a fact until there is proof that the quantities of Red 32 on oranges "are dangerous to public health" (R. 181). But a fair reading of what the Department representatives said gives no assurance that Red 32 is harmless when used solely for coloring oranges. Instead, the Department made it plain that the harmlessness of coloring oranges with Red 32 is not yet established, and will not be until further comprehensive animal studies are undertaken and completed. That was the very purpose of limiting the temporary legislation to a 3 year period. The portion of the Secretary's letter quoted in the opinion below (R. 184-185) makes this quite plain. Thus, it cannot be said with any real conviction that Red 32 is a harmless color even if it could lawfully be restricted to use solely on color-added oranges—which under the reasoning of the court below it could not be. And it most certainly is not a harmless color for unrestricted use in or on food (see Point I, A, *supra*, pp. 19-20).

The respondents argue that the animal proof of the toxicity of Red 32 was largely meaningless because the levels of color fed were not related specifically to the amounts of Red 32 man would likely obtain from color-added oranges.[19] They attempt to avoid the impact of the uncontradicted evidence, and the conclusive findings of fact, by showing that man would have to eat thousands of oranges each day to ingest an amount of

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[19] The argument is made that even table salt has an adverse physiological effect if taken in large enough amounts. The record shows that 2 or 3 ounces of salt would adversely affect man, but that is 56,669 to 85,048 milligrams, as compared with 100 milligrams of Red 32, the cathartic dose for dogs. The substances are in no real sense comparable. The only comparison shown on the record with a recognized poison is with carbolic acid (R. 220-221) and Red 32 is more toxic chronically than carbolic acid.

color comparable to that which killed and injured the test rats and dogs. The difficulty with such an analysis is that the comparisons drawn are based on levels of animal feedings which caused injury or death, not on levels which were safe for the test animals. Since no level of safe feeding for animals has yet been established by appropriate scientific study, and since 100 ppm (parts per million) in the diet of dogs, the lowest level fed, killed one of the dogs, there is simply no proper starting point for estimating a safe dose for man, and thus no factual basis for concluding that Red 32 on oranges is wholly without hazard.

The respondents, with no evidence in the record to support their claim of harmlessness, rely heavily on an analysis of the findings by a Dr. Gerwe, which was originally filed as a part of the exceptions to the proposed order (R. 112-115).[20] Dr. Gerwe's background has been in chemistry rather than pharmacology or toxicolgy. In his analysis, in the last paragraph, he states that "the feeding levels * * * employed in the experiments are * * * fantastically greater than the amounts or levels that a person might get by eating oranges or by

[20] A much more reliable scientific appraisal of this entire problem is the one done by an *ad hoc* Advisory Committee of the National Academy of Sciences—National Research Council, appointed to review the Food and Drug Administration Research Program on Coal-Tar Dyes. The Committee's report of June 1956 (in mimeograph only) includes a section entitled "Review of Toxicology and Pharmacology Research Program", pp. 7-13. It found the decertification of the three dyes justified, and indicated that decertification of some others may be justifiable on the evidence available. While the Committee indicated that the concept of "harmless" is unrealistic if levels of use are not specified, it noted that manufacturers assume they may safely incorporate in their products any quantity of a certified dye. No suggestion was made to withdraw the decertification of Red 32.

drinking the juice." They were "fantastic" only if their purpose is misunderstood. They were designed for the purpose of determining whether the colors under consideration could be regarded as "harmless", as the word is understood by a qualified toxicologist. They were the tests customarily employed by competent toxicologists for that purpose. The tests were not directed to the question of whether the amount of this color currently used for any single food purpose might be safely tolerated under the limitations of strict regulations. They were conducted to enable the Department to reach a sound judgment on whether Red 32 can be regarded as a harmless color for unrestricted use in the Nation's dietary.

In paragraphs 3 and 4 of his analysis, Dr. Gerwe compares the amount of Red 32 fed the rats in one of the experiments with the amount of oranges a human being would have to eat to obtain a comparable amount of the color (R. 113). Aside from the fact that man is much more susceptible to the effects of the color than animals and would obtain quantities of this color from other sources than oranges unless there were some lawful way to restrict its use,[21] it serves no purpose to

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[21] Exhibit 7 introduced at the hearing through Robert C. Evans, General Manager of the Florida Citrus Commission, has not been included in the printed record. It showed, however, that for the 1948-1949 season the weight of the colored oranges shipped from Florida that year was approximately one billion eight million pounds (based on a weight of 90 pounds per box of oranges). Louis Gardner MacDowell testified that the average amount of dye contained on whole oranges was approximately six parts per million. Assuming these oranges contained six parts per million of Red 32, that gives us approximately 11,000 pounds of this color which was used for coloring oranges, according to the respondents. This is the principal use for this color, yet the certification figures of the Food and Drug Administration show that for the past ten

compare one tenth of one per cent of the color which caused injury to rats with the amount of oranges a man would have to consume to be equally injured. At *this* level of consumption the color stunted the growth of rats, enlarged their hearts, and caused them to die. This was not a safe level of administration.

It was recognized both by the Secretary and by the court below that no safe level of feeding of Red 32 to test animals has yet been established. Congress enacted the temporary legislation—P.L. 672, 84th Cong., 2d Sess., 70 Stat. 512, *supra*, pp. 11-12, to allow time for the further exploration of the toxicity of Red 32. H. Rep. 1982, p. 3. Without evidence as to the precise toxic potential of Red 32 to test animals, there is no way to devise a safe tolerance for man.[22]

B. *The Secretary does not have the burden of showing danger.*

Instead of recognizing the absence of a safe level as an insuperable obstacle to the application of the tolerance provisions of Section 406(a), the court below forbade the Secretary to revoke his 1939 finding of the harmlessness of Red 32, until he acquired evidence to show that the color-added oranges would be dangerous to health. This means that the color on oranges is assumed to be safe until the contrary is proven. The burden is on the Secretary to prove danger.

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years the amounts of Red 32 certified have averaged 40,000 pounds. This leaves 29,000 pounds unaccounted for by the color estimated to be on the skin of oranges. (R. 155-156).

[22] The respondents asserted below that certain Canadian experiments had established a safe level for Red 32 at 300 ppm. But Canada followed the Secretary's example and took the three colors off its list on July 26, 1956. P.C. 1956-1148, revoking regulations B.06.025-.027, Canada Gazette, SOR/56-271 (Vol. 90, Part 2, p. 800).

This interpretation is clearly erroneous. If Section 406(a) is held applicable at all, the burden should be on the respondents to come forward with proof of safety. A toxic color is not to be tolerated on the negative evidence that no known injury to man has yet occurred. On the contrary, it cannot be tolerated until there is positive proof of safety. We should not wait for positive injury to man, but should view the law as a measure to prevent injury. As one scientist at the hearing put it: "It is imperative that the public, and not the food dyes, be given the benefit of any doubt." (R. 223). Colors should not remain on the harmless list, and in food use, when there is a reasonable doubt as to their safety. The Secretary is surely authorized to take into consideration the "margin of safety which the public interest required" in making his forecasts as to the future safety of a coal-tar color in food. See *United States* v. *Detroit and Cleveland Navigation Co.*, 326 U.S. 236, 240. He is not required to indulge "in hair-splitting speculation as to whether the amount of poison used may possibly have been so nicely calculated as not to kill or be of immediate serious injury". Landis, J., in *United States* v. *1,950 boxes of Macaroni*, 181 Fed. 427 (N.D. Ill.).

As Judge Hastie observed in reviewing other regulations issued by the Department in *Atlas Powder Co.* v. *Ewing*, 201 F. 2d 347, 355 (C.A. 3):

> One making a rule for the future which in practical effect will determine whether millions of people shall eat something every day may reasonably refuse to subject the general public to even slight risks and small deceptions. In these circumstances, the fact that administrative action has

been dominated by great caution but serves to emphasize the reasonableness of the Administrator's conduct.

There, the Administrator excluded from bread a chemical of doubtful safety—even though he was unable to conclude that it was deleterious—on the ground that to permit its use would not "promote honesty and fair dealing in the interest of consumers".

Here, the Secretary is concerned with chemicals that affect the heart, the liver, and other vital organs; with chemicals that profoundly affect growth processes; with chemicals of established toxicity. At the very least, before such substances are permitted into the national diet on food of widespread use, there should be expert testimony as to permissible tolerances. At the very least, assuming that the opinion below correctly interprets the statute, the Secretary must be presented with evidence that will show that safe tolerances can be established under Section 406(a), and he must consider the use of Red 32 on oranges in connection with the use of coal-tar colors on other products.

The initial determination as to the necessity and possibility of tolerances is for him to make, not the court. As this Court said in *Federal Security Administrator* v. *Quaker Oats Co.*, 318 U.S. 218, 227-228:

> The Act does not contemplate that courts should thus substitute their own judgment for that of the Administrator. * * *
>
> * * * Under such provisions we have repeatedly emphasized the scope that must be allowed to the discretion and informed judgment of an expert administrative body [citing cases]. These considerations are especially appropriate where the

review is of regulations of general application adopted by an administrative agency under its rulemaking power in carrying out the policy of a statute with whose enforcement it is charged. * * *

Contrary to this principle, the court below, instead of remanding the case to the Secretary to consider the promulgation of a tolerance for Red 32 on oranges, in accordance with Sections 406(a) and 701, erroneously promulgated the rule itself (R. 186-187).

CONCLUSION

For the foregoing reasons, it is submitted that the judgments of the court below should be reversed and the Secretary's order affirmed. Should the Court disagree with our contention that Section 406(a) is wholly inapplicable to coal-tar colors, the judgments of the Court of Appeals should be reversed with instructions to remand the case to the Secretary for appropriate proceedings under Sections 406(a) and 701.

Respectfully submitted,

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No. 27

In the Supreme Court of the United States

OCTOBER TERM, 1958

ARTHUR S. FLEMMING, SECRETARY OF HEALTH, EDUCATION AND WELFARE, PETITIONER

v.

FLORIDA CITRUS EXCHANGE, FRANK R. SCHELL, ET AL.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

REPLY BRIEF FOR THE PETITIONER

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I

THE FOOD ADDITIVES AMENDMENT APPROVED ON SEPTEMBER 6, 1958 DOES NOT AFFECT THIS CASE

A. After the petitioner's brief was filed, the Food Additives Amendment of 1958, Public Law 85–929, was approved. The earliest effective date of its enforcement provisions (Section 3) will be March 5, 1959 (Section 6).

The new amendment provides in pertinent part as follows:

> SEC. 402. A food shall be deemed to be adulterated—
> * * * (2) (*A*) if it bears or contains any added poisonous or added deleterious substance

(except a pesticide chemical in or on a raw agricultural commodity *and except a food additive*) which is unsafe within the meaning of section 406, or (*B*) if it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of section 408 (a), or (*C*) *if it is, or it bears or contains, any food additive which is unsafe within the meaning of section 409.* * * * [New material emphasized.]

"Food additive" is defined in Section 201 (s) as:

> * * * any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food * * *), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use * * *.

"Food additives" are declared to be unsafe unless their use is permitted by an exemption or a regulation prescribing the conditions under which such an additive may be safely used (Sec. 409 (a)).

Any person is authorized to file a petition to establish the safety of a food additive for its intended use, submitting among other things data to show what the

intended effect is and that full investigations have been made with respect to the safety of the additive (Sec. 409 (b)). The Secretary is directed to act on the petition by establishing the necessary regulation or exemption to guarantee safe use or by refusing to do so (Sec. 409 (c)). No such regulation may issue if the data fails to establish that the proposed use of the food additive will be safe, or if the data shows the additive would promote deception of the consumer or would otherwise result in adulteration or misbranding of food. And if a tolerance limitation is required to assure safe use, the tolerance is to be fixed no higher than is needed to accomplish the intended physical or technical effect (Sec. 409 (c) (3) and (4)).

The law requires the Secretary to consider the probable consumption levels for the additive, the cumulative effect of it, as well as of any chemically or pharmacologically related substances, in the diet, and to apply appropriate safety factors in evaluating the animal experimentation data (Sec. 409 (c) (5)).

The prime purpose of this amendment was to prohibit the use in food of additives before their safety for their intended use had been adequately investigated and firmly established. And if the safety could be thus established, the additive was no longer forbidden solely because it was a poisonous or deleterious substance. Safe amounts may be tolerated at the lowest levels required to accomplish the intended effect.

B. We have difficulty in understanding why respondents believe that this new law aids their cause.

In the first place, it has no applicability to coal-tar colors. Neither respondent contends otherwise, but they seek in some way to use the new law to influence the meaning of "harmless" in Section 406 (b). In the second place, the new law makes it clear that it is the duty of the user of an additive to prove that the additive will be safe. Respondents cannot show this as to Red 32.

1. We believe the new provisions wholly inapplicable to coal-tar colors.[1]

Congress did not amend Section 406 (b), which deals specifically with coal-tar colors, on which the Secretary's order in this case was based. Indeed, the very same Committee which developed the new law, the House Committee on Interstate and Foreign Commerce, had before it H. R. 8945, a bill to authorize the Secretary to establish safe tolerances for coal-tar and other color additives. The Department of Health, Education, and Welfare reported on the bill by letter dated June 27, 1958. No hearings were held, and the bill died with the adjournment of Congress.[2]

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[1] The press release by the Department of Health, Education, and Welfare on the new law contains the following sentence: "Antioxidants, mold inhibitors, rancidity prevention agents and other preservatives, emulsifiers, stabilizers, extenders, colors, flavors, bleaching agents and thickening agents are examples of the type of additives which are covered." It does not say that coal-tar colors are covered.

[2] The Department of Justice also reported on this bill in June 1958, and told the Congress that its enactment would render the present litigation moot. But the Food Additive Amendment, which does not apply to coal-tar colors, does not make the litigation moot. So long as Section 406 (b) remains in the law, this case retains the importance that brought it here.

This separate consideration of the status of coal-tar colors is consistent with the Congressional policy followed in Section 406 (a) and (b), as discussed in our main brief. And until Congress revises the policy of allowing the certification only of coal-tar colors that are wholly harmless, the provisions of Section 406 (b) must be followed.

2. But even if the Secretary has power to permit use of a coal-tar color under tolerances, and even if the new legislation can be said to suggest a policy to be followed in that situation, the new legislation is not yet effective and the facts do not exist on which a safe tolerance for Red 32 can be established even for oranges.

In an effort to minimize the poisonous character of Red 32, respondents assert that all that is shown on this record is that Red 32, like all other substances, is toxic when consumed in massive and excessive amounts bearing no relation to the amount likely to be consumed from color-added oranges.

The amounts tested, 100 ppm. and 400 ppm. in dogs and 1000 ppm. and 2500 ppm. in rats, are in no real sense massive doses. They were chosen by qualified pharmacologists as proper amounts to be added to the test diets to answer the question whether the dye could be regarded as harmless for unrestricted use in food—whether in the diet it could be regarded as innocuous. These tests are clearly relevant to the question the Secretary was called upon to decide.

In contrast, respondents base their entire claim that Red 32 is harmless when used on oranges on certain claimed admissions of the Commissioner of Food and

Drugs and of Secretary Folsom. These are drawn from a letter to Senator Smathers, a letter to Congressman Haley, a press release, and testimony and a report on the bill, H. R. 7732, 84th Cong. (Fla. Cit. Br. 21–22; Schell Br. 39, 60–61, 84–85), which was enacted into the temporary legislation discussed on pages 10–12 of our main brief. A fair reading of these materials, all outside the record, establishes these salient facts:—Red 32 is a poisonous substance when fed to laboratory test animals; exactly how poisonous it is not known because the lowest level fed to the test dogs—100 parts per million—killed one of the dogs; until the precise toxicity of the color is established, together with its probable intake under all likely patterns of consumption, we cannot say that there is a likelihood of injury to man from consumption of color-added oranges; nor can we say with assurance that the practice is a wholly safe one.[3] The fact that no injuries to man have been attributed to Red 32 on oranges is, as the Secretary found (Finding 9, R. 163–164), of little significance "because few people know what colors they are eating" and the delayed toxic effects to vital organs and processes would not have been attributed to the color even if caused by it.

Under the new legislation, this kind of inconclusive evidence of safety would not result in permission to use an additive. It was to deal with precisely this

[3] While both respondents repeatedly assert that the Department of Health, Education, and Welfare admits there is no possibility whatever of harm from color-added oranges, the most that can be said is that the likelihood of harm from this single food is not believed to be great, but is actually unknown (cf. Fla. Cit. Br. 53).

sort of situation in the case of food additives in general that the Food Additives Amendment of 1958 was enacted. There was an important loophole in the Federal Food, Drug, and Cosmetic Act which permitted the use of chemicals in food though their toxicity was either unknown or uncertain. The Government could not prevent the use of a chemical in food until it was prepared to prove that the substance was in fact a poisonous or deleterious one. This meant that the questionable chemical could be used without evidence that it was safe; the Government had the burden of conducting the necessary scientific investigation to determine whether the chemical was a poisonous or deleterious one, and while the scientific investigation of its toxicity was underway it could be used. If the chemical finally turned out after testing to be poisonous, it could be removed from the diet, but only after the harm had been done. H. Rept. 2284, pp. 1–2, 4–5; S. Rept. 2422, pp. 1–3, 6–7, 85th Cong., 2d Sess.

The new law will relax to some extent the stringent prohibition against all added poisonous and deleterious substances, discussed on pages 36–41 of our brief.[4] But this same new law will exclude from the food supply all chemical substances that are not definitely known to be safe for their intended use. All questions of doubt are to be resolved against the

[4] Section 406 (a) will now apply to added poisonous and deleterious substances that accidentally contaminate foods during production and in the manufacturing processes. Intentional food additives used to accomplish some desired physical or technical effect in the food will be controlled by the new law. Section 409 (b) (1) and (c) (3), Public Law 85–929, Section 4.

chemicals and in favor of the consumer. Proof positive is needed before the chemical can be used.

So even if the new statute applied to Red 32 on Texas and Florida oranges—which it does not—the practice could not be tolerated until there can be an affirmative showing that it is entirely a safe one. Congress, by the temporary legislation, gave the growers a moratorium of three years to develop a color that is not toxic or to explore further the toxicity of Red 32 to obtain the facts on which a safe tolerance could perhaps be based (Pet. Br. 10–11). This further evidence clearly would be required before Red 32 could be tolerated as a food additive.

II

RESPONDENTS' ATTACKS ON THE FINDINGS OF FACT ARE WITHOUT MERIT

1. Both lower courts (the Second Circuit and the Fifth Circuit below) have sustained the Secretary's evidence. Nonetheless, respondent Schell attacks the critical finding that no safe level of dosage for Red 32 has been established even for the test animals, by asserting that the test was improperly conducted in bad faith, and that the results are refuted by other experiments both before and after[8] the test in question (Schell Br. 15, 32–39). The Citrus Exchange complains that the findings ignored certain essential

[8] The subsequent test relied upon is made an appendix to Schell's brief. It was done by Canadian investigators. It involved rats, not dogs. It lasted only 20 and 44 weeks, instead of the life span of two years, and could not refute the dog studies. We discussed Canada's action on these three colors in footnote 22, p. 49, of our main brief.

findings of fact, which he made on uncontroverted

testimony (Br. 11), and that the Secretary failed to meet the burden of proof (Br. 15). A portion of the testimony is quoted (Br. 17–19) out of context to cast doubt on the findings. And the significance of the findings is challenged by the Gerwe analysis (Br. 23), which wholly fails to take account of the injury to the test dog at 100 ppm. Finally, there is a reproduction of testimony from the 1939 hearings (Br. 30–32) which implies that no coal-tar color is harmless and suitable for use in all kinds and classes of foods, drugs, and cosmetics. A full reading of the old testimony shows that the single exception the witness was discussing was coal-tar colors to be applied to the area of the eye.

It is, of course, true that the tests on which the Secretary's findings were based were not designed to show whether color-added *oranges* are safe. They were designed to explore whether the colors were harmless for *unrestricted* use in food, drugs, and cosmetics. The evidence shows that they are not (R. 217). The sole scientific witness said:

> The dyes in question are at present being certified for use in foods, drugs, and cosmetics, and the data which we presented in these exhibits have shown that they are not harmless for use in all of those products.

For the reasons set forth in our main brief, we believe that the Secretary has under the statute no power to determine whether Red 32 would be safe on oranges alone; authority to make that determination must come from Congress. But, in any event, as developed *supra*, pp. 5–8, it is plain that whether

Red 32 might be safe for use on oranges alone cannot now be determined on the known facts. With an amended law and a sound factual basis on likely consumption levels and the true toxic potential of the color, it might be possible to fix a safe tolerance for Red 32 on one or more foods. But no such law or such facts now exist.[6]

2. Respondents also argue that all coal-tar colors are toxic; that Congress knew this in 1938; and that therefore it is unreasonable to prevent the use of coal-tar colors which are not wholly safe. This is not so. The legislative history and administrative background of the coal-tar color certification provisions plainly show that both Congress and the administrative officials thought that "most", but not all, coal-tar colors were toxic. The conception of the law was to forbid use of the toxic colors, while permitting the unrestricted use of the innocuous ones.

That policy has been followed since 1907. The Secretary, in reporting on H. R. 8945, *supra*, p. 4, recognized that new scientific studies are proving this to be a stringent test and are eliminating colors from the list which have long been on it. This is why the Secretary asked fresh Congressional guidance in this field. Several colors remain on the list, however, under the harm-

---

[6] Finding 10 is cited by respondents as saying that colors are used in so many foods that the establishment of proper tolerances would be impossible (Schell Br. 51). What the finding says, however, is that there is now no proper factual or legal basis for establishing a safe tolerance for the three colors in a variety of foods.

less classification. If the use of harmful colors is to be permitted, Congress must grant the authorization.[1]

Respectfully submitted.

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NOVEMBER 1958.

---

[1] Respondents argue that it is unreasonable to bar all use of a toxic coal-tar color when toxic ingredients such as arsenic may be used in their manufacture (Schell Br. 63). The tolerances for arsenic, etc., are, however, fixed at levels which give assurance that the color, when certified, is itself harmless. The test of harmlessness in the statute applies to the finished coal-tar color, not to the ingredients comprising it. The legislative history of the coal-tar color provisions shows that Congress intended the Secretary to so limit the necessary impurities in coal-tar colors that the colors themselves would be harmless.

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In the Supreme Court of the United States

OCTOBER TERM 1957

MARION B. FOLSOM, Secretary of Health, Education and Welfare,
Petitioner,
-vs-
FLORIDA CITRUS EXCHANGE, et al,
and
FRANK R. SCHELL,
Respondents.

No. 27

BRIEF OF RESPONDENT FRANK R. SCHELL IN OPPOSITION TO PETITION FOR WRIT OF CERTIORARI.

• • • • •

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In the Supreme Court of the United States

OCTOBER TERM 1957

MARION B. FOLSOM, Secretary of Health, Education and Welfare	)	
Petitioner,	)	
-vs-	)	
FLORIDA CITRUS EXCHANGE, et al,	)	No. 703
	)	October Term 1957
and	)	
FRANK R. SCHELL,	)	
Respondents.	)	

Brief of Respondent Frank R. Schell in Opposition to Petition for Writ of Certiorari

Preliminary Statement

The respondent, Frank R. Schell, respectfully presents this brief in opposition to the petition of Marion B. Folsom, Secretary of Health, Education and Welfare, for writ of certiorari.

In this brief the following abbreviations and designations will be used:

"Secretary" refers to Hon. Marion B. Folsom, Secretary of Department of Health, Education and Welfare;

"Respondent" refers to Frank R. Schell;

"PB—" refers to pages of Secretary's petition and brief;

"R——" refers to pages in Record before C.C.A., Fifth Circuit;

"JA—" refers to pages in Joint Appendix before C.C.A., Fifth Circuit;

"A" refers to page number of Appendix in this Brief;

"USDA" refers to U. S. Dep't of Agriculture;

"F&DA" refers to U. S. Food and Drug Administration;

"The Act" refers to Federal Food, Drug and Cosmetic Act;

"Color Added" refers to a process for coloring oranges with a coal-tar color;

"Red 32", or similar words, refers to FD&C Red No. 32 and other coal-tar colors.

"Dunn, p.——," refers to pages in Charles Wesley Dunn's work "Federal Food, Drug and Cosmetic Act" (1938), compilation of the official records of the Congress, which we make use of in this brief in discussing the legislative history of the Act.

"p.p.m." refers to "parts of color per million parts of food so colored."

Errata in "Record"

At p. 244, line 12, the figures "710/0" should read "7/100".

At p. 247, line 8, par. numbered "2"; 5th word "do" should be "so".

At p. 251, the third complete paragraph reads:

> 'On January 19, he said, the administration would open formal hearings **on the subject of whether orange color with coal-tar dyes."**

Whereas the same should read:

> "On January 19, he said, the administration would open formal hearings **on the subject of whether orange growers would be allowed to continue tinting their fruits orange color with coal-tar colors."** See correct quotation, par. 2, p. 252.)

Opinions Below

The Secretary's order (R 281) appears in 20 F. R. 8493. The opinions of the Court of Appeals, Fifth Cir-

cuit, are reported in 246 Fed. 2nd 850 and appears PB 25-52. The opinion of the Court of Appeals, Second Circuit, is reported in 236 Fed. 2nd 866 and appears in the appendix to this brief at pages A-1 to A-7.

Jurisdiction

The Secretary seeks to invoke the jurisdiction of this Court on the ground that the decision of the Circuit Court, Second Circuit, and the decision of the Circuit Court, Fifth Circuit, are in basic conflict. It will be the contention of respondent that no basic conflict exists and that the decisions of the two courts are basically in harmony as to the law.

Statutes Involved

The Federal Food, Drug and Cosmetic Act, as amended, 52 Stat. 1040, 70 Stat. 512 (21 U.S.C. 301, et seq.) provides in all of its pertinent parts as follows:

"Sec. 402. A food shall be deemed to be adulterated—

(a) (1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health; or (2) if it bears or contains any added poisonous or added deleterious substance, **except a pesticide chemical in or on a raw agriculture commodity**, which is unsafe within the meaning of section 406, **or if it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of Section 408 (a)**; or • • •

"(c) If it bears or contains a coal-tar color other than one from a batch that has been certified

in accordance with regulations as provided by section 406; **Provided that this paragraph shall not apply to citrus fruit bearing or containing a coal-tar color if application for listing of such color has been made under this act and such application has not been acted on by the Secretary, if such color was commonly used prior to the enactment of this act for the purpose of coloring citrus fruit:** Provided further, That this paragraph shall not apply to oranges meeting minimum maturity standards established by or under the laws of the States in which the oranges were grown and not intended for processing (other than oranges designated by the trade as 'packing house elimination') the skins of which have been colored at any time prior to March 1, 1959, with the coal-tar color certified prior to the enactment of this proviso as FD&C Red 32, or certified after such enactment as External D&C Red 14 in accordance with section 21, Code of Federal Regulations, part 9: And provided further, That the preceding proviso shall have no further effect if prior to March 1, 1959, another coal-tar color suitable for coloring oranges is listed under section 406." (21 U.S.C. 342)

• • • •

"Sec. 406 (a) Any poisonous or deleterious substance added to any food, except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice shall be deemed to be unsafe for purposes of the application of clause (2) of section 402 (a); but when such substance is so required or cannot be so avoided, the Secretary shall promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health, and any quantity exceeding

the limits so fixed shall also be deemed to be unsafe for purposes of the application of clause (2) of section 402 (a). While such a regulation is in effect limiting the quantity of any such substance in the case of any food, such food shall not, by reason of bearing or containing any such added amount of such substance, be considered to be adulterated within the meaning of clause 1 of section 402 (a). In determining the quantity of such added substance to be tolerated in or on different articles of food the Secretary shall take into account the extent to which the use of such substance is required or cannot be avoided in the production of each such article, and the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances.

(b) The Secretary shall promulgate regulations providing for the listing of coal-tar colors which are harmless and suitable for use in food and for the certification of batches of such colors, with or without harmless diluents" (21 U.S.C. 346).

• • • •

"Sec. 701 (f) (1). In a case of actual controversy as to the validity of any order under subsection (e), any person who will be adversely affected by such order if placed in effect may at any time prior to the ninetieth day after such order is issued file a petition with the Circuit Court of Appeals of the United States for the circuit wherein such person resides or has his principal place of business, for a judicial review of such order***"

• • • •

"(3) The court shall have jurisdiction to affirm the order, or to set it aside in whole or in

part, temporarily or permanently. * * * The findings of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive.

"(4) The judgment of the court affirming or setting aside, in whole or in part, any such order of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari * * *" (21 U.S.C. 371).

(Emphasis supplied indicates portions omitted from Secretary's quotation of the Act "in pertinent part." PB 3-5).

Questions Presented

We respectfully submit to this Court that the questions submitted by petitioner do not, in our opinion, correctly set forth the issues before this Court and we submit as questions presented, the following:

(1) Whether there is any basic conflict between the decision of the Circuit Court of the Second Circuit and the decision of the Circuit Court of the Fifth Circuit.

(2) Whether the Circuit Court, Fifth Circuit, erred in holding that Red 32 is "harmless and suitable for use in foods," for coloring of oranges only, within the contemplation of the Food, Drug and Cosmetic Act.

(3) Whether the Circuit Court, Fifth Circuit, erred in holding that the Secretary had the authority under the Federal Food, Drug and Cosmetic Act to fix tolerances for use of coal-tar colors on or in specified foods.

(4) Whether the Circuit Court, Fifth Circuit, erred in holding that the Secretary had authority under the Federal Food, Drug and Cosmetic Act to limit the use of Red 32 to use in coloring oranges.

Statement Of The Case

The Color Added process was perfected in 1933, (R. 217) but due to an improper ruling by Mr. Walter G. Campbell, then Chief of F&DA, that the process could not be used at all (R. 221) did not go into commercial use until the Fall of 1934, after a ruling by the Solicitor for U.S.D.A., dated February 28, 1934, settled the points of law concerned, overruling Mr. Campbell's total prohibition of use, but requiring the labeling "Color Added" (from which the process derived its name) on the peel of each orange. (R. 222).

The history of Color Added is recited at R. 214-227. We respectfully request and urge that the Court carefully consider that record of:

(1) The early attempted total prohibition of use by the Chief of F&DA, alleging the use of color to deceive the consumer, which charge was completely refuted and overruled during the series of hearings during 1934, 1935, 1936, and 1937, all designed to induce the Secretary of U.S.D.A. to uphold that total prohibition of use (R. 220-223);

(2) The attempts of F&DA to procure legislation that would enable it to out-law the Color Added process by withholding certification of food colors indispensable to the operation thereof and the defeat of all such attempts (R. 224-227);

(3) The final agreement of Mr. Campbell and Hon. J. Hardin Peterson, then Representative from the First Congressional District of Florida and now Counsel in the instant case, relating to terms of the Act (R. 227) and

(4) The subsequent drafting of amendments to the pending legislation (which amendments were finally incorporated in Sec. 402 (c) and

Secs. 406 (a) and 406 (b) of the 1938 Food, Drug and Cosmetic Act as enacted) (R. 228) each of said amendments (as then concurred in by the then Chief of F&DA) having the specific purpose of preventing F&DA destroying the Color Added process by denying certification to colors indispensable to the operation thereof.

There was no further interference with Color Added by F&DA until 1953. From 1937, until now, there has never been a complaint to (or by) F&DA that the process was being improperly operated or improperly used or that the States of Florida and Texas were not properly policing the use of the process. Nor has there been so much as a suggestion that the health of any person has ever been adversely affected by eating Color Added oranges.

As will hereinafter be shown (p. 28-29) the word "harmless", in regulations re food colors, had been used and construed in its **relative** sense from the first regulations issued in 1907. Congress used the word in that sense in, and this interpretation and construction continued under, the 1938 FD&C Act. Thus, at the very first hearings re-certification of food colors under the 1938 Act, held in 1939, the word "harmless" was very clearly construed, by the then head of the Division of Pharmacology of F&DA, as being used in a relative sense, i.e., harmless in the amounts of ordinary usage (R. 170, 177-178) and Red 32 was certified and Orange 2, previously certified under the name Orange SS, was recertified. In 1940, following those hearings, F&DA issued its "Coal Tar Color Regulations" (SRA, FDC 3) pursuant to provisions of 1938 Food, Drug and Cosmetic Act, which Regulations carried that interpretation into effect, and established tolerances for coal-tar colors, as hereinafter shown (p. 45-46).

Thereafter, until the spring of 1953 — 15 years —

such certification continued without any question of the entire harmlessness of that color.

Moreover, on Oct. 13, 1952, the Associate Commissioner of U.S. F&DA addressed a letter to Mr. Randall Chase, of Sanford, Florida, which began (R. p. 72):

> "Let me say at the outset that this Administration is in agreement with your conclusion that the use of added color is inherently deceptive and is contrary to the interests of both consumers and producers."

The above quotation appears in a brief filed in the Department proceedings (R. p. 72). In the next sentence, discussing additional statements made in the Associate Commissioner's letter to Mr. Chase, but not quoted, the Brief continues:

> "We are in entire accord with that administrative position. We are in disagreement, however, with **the view apparently taken at that time that the legislative history of the Act requires a conclusion that the law does not ban the use on oranges of such dyes** as create an economic cheat upon the consumer".

Thus, as late as October, 1952, we find F&DA adhering to that construction of the word "harmless" in its **relative** sense, as being the intent of the Congress.

Of course, if the color created "an economic cheat" it was the use, not the color, that would be subject to attack. If the color was "harmless" according to the intent of Congress, the color was eligible for certification although the use made thereof might be subject to criticism — but no such criticism has been or could be raised by F&DA in these proceedings, for that charge had been completely refuted back in 1933-37.

Then, in about March of 1953, the manufacturers of Red 32 were informed that F&DA was re-examining the whole question of possible toxicity of all certified

coal-tar food colors, but such advices were accompanied by assurances that F&DA understood and appreciated the importance of the Color Added process to the citrus industry of Florida and Texas, and that such re-examination was in no wise hostile thereto (R 250-251).

F&DA then initiated a series of abbreviated tests of Red No. 32, which ran for 173 days only, and, on the strength of these abbreviated tests, F&DA then repudiated the results had from a series of tests over a period of six years (1938-1944) (JA 85-86) and, in about November of 1953, informed the color manufacturers that F&DA proposed to delete Red 32, Orange 2 and Orange 1 from the list of certifiable dyes, which, of course, would prohibit use of the Color Added process, since only certified food colors may be used in or on foods. F&DA protested their regret at being forced to take such action, but asserted their lack of alternative in view of their Counsel's construing the word "harmless" in the Statute as requiring "zero toxicity". (R. 256-257).

On January 1st, 1954, **Commissioner George R. Larrick,** in an interview with a Washington newspaperman, **identified the purpose of the hearing** to be held on January 19, 1954, as being the determination of **"whether orange growers would be permitted to continued tinting their fruits orange color with coal-tar dyes." (R 251).**

When this Respondent learned, on December 18, 1953, of the real purpose of the hearings, and especially after the confirmation by Commissioner Larrick on January 1st, 1954, it was then far too late to employ Counsel and inform them as to the ramifications of a highly technical subject matter and be properly represented at the hearing on January 19, 1954, and this Respondent necessarily was not represented (R. 210-211). Also, feeding tests at proper levels, having some relation to public health, and analyses to determine the color content of all

foods colored with the three colors, would have required a minimum of one year's time. Some data was presented by Counsel for the color manufacturers, from the Florida Citrus Commission, as to amount of added color deposited in the peel of Color Added oranges (4 parts of color per million parts of whole orange); in the juice, (7/100 of 1 ppm); and in candied orange peel (7.4 ppm) and marmalade (1.8 ppm) when made from Color Added oranges (JA. 45). No other presentations by Respondent or the citrus industry were possible, for reasons stated.

At the hearing on January 19, 1954, while admitting (JA 25 - 26) that they had no information as to harmfulness of the colors at "levels of ordinary normal conditions of use", F&DA presented data which proved only that test animals can be made ill by the colors when fed amounts thereof which are vastly in excess of normal uses in foods, a result that would, of course, follow from like excessive consumption of any other substance possible of being ingested by man. (JA. 6-39; Exhibits JA. 49-93).

On February 7, 1955, Mr. George P. Larrick, Commissioner of Food and Drug Administration, addressed a letter to Florida's Senator George A. Smathers, reading, in pertinent part, as follows (R. 236):

> "The proposal to remove these coal-tar colors, including FD&C Red No. 32, from the list of colors eligible for certification for use in food results from the requirements of the Pure Food Law that only colors that are harmless are eligible for certification. Recent investigations show that these colors, when fed in substantial amounts, show evidences of toxicity. **There is, however, no evidence that, in the amounts used, and in the manner of use, in the coloring of citrus fruits, the product so colored is not safe for human consumption.". (Emphasis supplied).**

In his statement, on February 10, 1956 ("Hearing before a Sub-Committee on Interstate and Foreign Commerce, H.R., 84th Congress, 2d. Session, on H.R. 7732") (which became P.L. 672) Mr. Larrick said (p. 18):

> "Considering all of the information so far available — and bearing in mind particularly **the minute amount** of the dye likely to enter the human diet as a result of its use on oranges — we cannot say that its continued use on oranges, not intended for processing, would pose a hazard to the public health." (Emphasis supplied).

This Respondent, on March 5, 1955 presented his petition to intervene, in his own name, along with Exceptions and Brief and petition to reopen taking of testimony (R. 209-251) **all within the required time for pleading to the proposed Order.** The Exceptions, Brief and Petition presented matters and things that were self-evidently important and necessary to any proper consideration of the Proposed Rule Making (R. 209-213).

Respondent's pleadings were admitted to the record but his petition to reopen the proceedings, so as to give Respondent and the Florida citrus industry their day in Court, was ignored.

On November 10, 1955, the Secretary issued the final Order appealed from and there followed the proceedings in Fifth Circuit Court of Appeals and the decision of July 12, 1957, which held (Chief Judge Hutcheson dissenting) (1) that the word "harmless" should be construed in accordance with the rule laid down by the Supreme Court in **U.S. vs. Lexington Mill & Elevator Co.** (232 U.S. 399); (2) that the Secretary has the power to fix maximum limits of use (tolerances) for coal-tar food colors and (3) that the Secretary has and has exercised the power to limit the use of a specific color to one specific usage, and ordered the Secretary to proceed accordingly.

F&DA filed their petition for rehearing, which was denied by memorandum decision, Per Curiam, on August 28, 1957, Chief Judge Hutcheson again dissenting.

The mandate issued on October 12th and F&DA are now prosecuting their Petition to this Court.

Before proceeding to our argument we find it necessary to first correct certain

Errors in Petition for Certiorari.

At lines 5-8, Second paragraph, p. 13 of Petition, referring to the decision of Fifth Circuit Court, it is said:

> "It effectively defeats the object of Congress — in passing P.L. 672, the temporary legislation — of stimulating the color industry to develop new and safer coloring."

This is directly contrary to the statement in Committee Report on H.R. 7732, which became P.L. 672 (Senate Report 2391, June 29, 1956, 84th Congress, 2d Session) which reads:

> "Inasmuch as the judicial proceedings referred to above have not as yet been concluded, **the committee wants to make it clear** that if it is finally judicially determined that the Secretary of the Department of Health, Education and Welfare already has the power to certify FD&C Red No. 32 for use on the exterior of oranges, **the instant legislation is not intended to limit or modify that power.**" (Emphasis ours).

Again, the petition, beginning at "B", p. 15, through first complete par. on p. 16, urges this Honorable Court to grant its writ of certiorari because:

> "* * * Congress intended by P.L. 672 to press the color industry and the orange growers into prompt development of a harmless color or at least into scientific research which might pro-

vide a sound factual basis for a safe tolerance for Red 32 on oranges. * * *

"The decision below means, however, that the industry and the growers can rest on the Fifth Circuit judgement and do nothing * * * There is now no need for the industry to institute studies or to take action. **On the other hand, the scientific evidence to support the course of action required of the Secretary by the Court below does not now exist, and the investigations to obtain it will involve considerable expense and require at least two years after the study is commenced.** If the Secretary really does have the burden which the decision below c a s t s upon him, he should know that now. If, as we think, the burden is properly on the industry, the decision below, under which the industry need do nothing, should not be allowed to stand."

Thus it is sought to show to this Honorable Court that the Secretary fears, and has reason to fear, that, by reason of the Fifth Circuit's decision:

The color industry and the citrus industry ("citrus industry" includes proponents of the Color Added process) will be released from the compulsion the Congress intended to put upon them to undertake:

(a) Prompt development of a harmless color for oranges, or, at least,

(b) Scientific research which might provide "a sound factual basis for a safe tolerance for Red 32 on oranges;" and

(c) That, accordingly, the color industry and citrus industry will do nothing to those ends unless that decision be reversed; and

(d) An improper burden of work and expense, for (b), above, will thereby be imposed upon the Secretary.

We first respectfully submit that the Secretary did not, as asserted at "5", pp. 10-11 of Petition, win approval from the Congress as to his opposition to the Bill introduced as H.R. 7732. The fact is that Commissioner Larrick conferred with Hon. J. Hardin Peterson, Counsel for the citrus industry, before the Committee meeting, to talk compromise, Mr. Larrick's principal desire being to limit continued use of Red 32 to a perod of three years, which the industry readily accepted, since it afforded ample time to complete the research program that had then been under way since about May of 1954, and ample time in which to conclude this litigation.

The Committees of the House and Senate, therefore, did not decide any contest in the Secretary's favor, because there was no contest to be decided, but, instead, approved a non-controversial amendment which had the blessing of both the industry and F&DA. The Secretary's letter, stating his position, was dated February 13, being three days after the Committee hearing.

We respectfully request that the Court note these statements, made by Hon. J. Hardin Peterson, representing the Florida and Texas citrus industry, to the House Committee (Mr. Larrick being present) (Hearing, Supra, p. 15 at pp. 7-9 of transcript.)

> "Since I came here, Dr. Larrick of the Food and Drug Administration has shown me a statement which he is going to make. That statement will help us in our problem.
>
> • • • •
>
> "•• I will not get into the presentation, but with your permission I will put my statement in the record, because Dr. Larrick has told me

that he is willing to continue the certification of this color for 3 years. The formal report is being prepared, and he has a statement which he is going to give to the committee this morning. That will give us the time to come up with research and it will not throw the industry in a turmoil.

"Mr. Dies, 'That will eliminate the necessity for legislation?

"Mr. Peterson. No, sir, we will need legislation, but they are going to agree to it. They are going to agree to the legislation, limited to 3 years instead of indefinitely. With that, I think that we will be able to get this without trouble. We are in accord on that.

• • • •

"Mr. Peterson. Now, that is roughly the situation. **• • • I do not think I ought to argue the case if it looks like I have won it".**

Mr. Larrick thereafter stated to the Committee (p. 17):

"I am particularly glad, on my first appearance before this committee, since I became Commissioner, that it apparently will be a non-controversial hearing."

It is likewise respectfully submitted that the Congress had no intent, or occasion for intent, to press the color industry or the citrus industry to do anything whatever, the Congress being fully informed and advised, at the above mentioned Hearing had on H. R. 7732 (which became P.L. 672) that such work was then already well under way, and that no expenditure of time or money therefor, by the Secretary, was contemplated.

At line 13, p. 19 of the transcript of that "Hearing", we find this statement by the Chairman:

"I understand that under the terms proposed, there would be an amendment to the bill limit-

ing it to a 3 year period, during which time **growers and users of this color will make tests and conduct examinations and experiments** to determine whether **a substitute color** can be used." (Emphasis ours).

The Court is requested to note, further, this quotation from Committee Reports (H.R. Report No. 1982, Senate Report No. 2391, 84th Congress, 2d. Session):

> "However, the Committee concluded that this legislation should be limited to a maximum period of 3 years. This will allow time for the necessary scientific studies in the development of a harmless synthetic color. **The Committee received testimony that these studies are well under way and promise to yield good results.** The bill, as amended, will also allow time for a further exploration of the toxicity of FD&C Red 32. Before a final conclusion about the precise toxicity of this color can be drawn, it is necessary to conduct comprehensive scientific studies of chronic toxicity with laboratory animals over their life span. **This will involve feeding tests at levels relating to the quantities of the color that might enter man's diet from his consumption of colored oranges.** Such tests and studies will require approximately 3 years and **the industry is expected to make these studies during this period.**"

We will now discuss the above allegations of the Secretary's Petition under the listed headings:

The alleged intent of the Congress to press the industry to undertake: (a) Prompt development of a harmless color for oranges.

The Solicitor General; and Mr. William W. Goodrich, Assistant General Counsel, Department of Health, Education and Welfare; and Mr. George P. Larrick, Com-

missioner of Federal Food and Drug Administration, have, through Senator Spessard L. Holland, of Florida, authorized us to say to this Court that they have no objection to the recital of certain matters and things, from outside the record, re the industry's program for research as to a new color, in response to this allegation. We now inform the Court of the facts relative thereto:

The officials of F&DA have been kept fully informed and advised, at all times since the early months of 1954, that the citrus industry was then instituting, and has ever since been vigorously prosecuting, a complete program of research as to the toxicity of a new color, now known as Citrus Red No. 2, to replace Red 32 (and Orange 2, so far as coloring oranges is concerned); that this research has gone forward unceasingly and had been completed some months before the Secretary's Petition was written; that application for certification is now being prepared. (That application will likely have been filed with F&DA before this Brief is filed with this Honorable Court.)

F&DA were consulted, in early 1954, as to levels of feedings to be followed, i.e., ratio of color to food. The officers of Pharmacological Division of F&DA suggested and advised that such research include feeding trials at 1.0 per cent, 3.0 per cent and 5 per cent (10,000, 30,000 and 50,000 parts of color per million parts of food). The industry acceded, although well knowing (as does F&DA) that it is impossible, to this time, to formulate a coal-tar color having "no effect" when fed at ratios of 30,000 to 50,000 p.p.m. When the adverse results to be anticipated from feeding at those fantastic levels were had, the tests at those levels were discontinued.

Feeding tests were continued at lower levels and, when completed, the results showed a "no effect level"

at 1,000 p.p.m., being at least 250 times and, quite possibly, 500 times the amount of color that will be deposited in the peel of an orange colored therewith, as Citrus Red No. 2 has a much greater tinctorial power than Red 32, of which only 4 p.p.m is found in the peel of the orange.

While these feeding trials were under way, the officials of F&DA suggested metabolism and excretion tests (which, apparently, they had not deemed necessary theretofore, when making their own tests) and this, also, was done at an additional cost of $8,000.00.

At a preliminary conference had with the Pharmacological staff of F&DA in February of 1957, when all results had to that time and work still in progress were fully reported to F&DA, the pharmacologists of the independent testing laboratory in charge of those tests stated that the new color had only ten per cent of the possible toxicity of Red 32 and F&DA staff pharmacologists went so far as to concede that the new color had but twenty per cent of the toxicity of the color they had certified as harmless for fourteen years before asserting, after October 13, 1952, that it was not "harmless."

At that conference, however, Dr. Arnold J. Lehman, Chief of Pharmacological Division of F&DA, while conceding that the data then available was likewise ample for the establishment of tolerances (if authorized by the law as construed by F&DA) went on to say that the new color would not be eligible for certification "under existing regulation", (i.e., under F&DA's interpretation of the word "harmless" as requiring "zero toxicity") in view of adverse effects had at those high levels of color to food.

We have been informed by Dr. Lehman, in effect, within the past few months, that it will not be worth while for the industry to file an application for certification of the new color Citrus Red No. 2, in view of the

adverse effects shown at the higher levels of feeding, which render the color non-certifiable, according to F&DA's doctrine of "zero toxicity".

This means, of course, that neither Citrus Red No. 2, nor any other new coal-tar color, can ever be certified and that every coal-tar color presently on the list of certifiable colors must be banned, since none of said colors can meet and pass a test for "zero toxicity", when fed at 30,000 to 50,000 p.p.m. The coal-tar color industry would thus be destroyed, and the citrus industry would be reduced to chaos (R. 47-10 to 47-12).

The amounts paid to independent research laboratories for such research, to December 31, 1957, was $122,478.00, of which this Respondent has paid $22,495.60. Other development and research costs, for research conducted by color manufacturers and by the industry, in their own laboratories, comes to approximately $48,296.-14, or a grand total of $170,774.14, for research as above recited.

The alleged intent of the Congress to press the industry to undertake: (b) Scientific research which might provide "a sound factual basis for a safe tolerance for Red 32 on oranges".

The attention of the Court is again respectfully directed to the language of the Petition (p. 16) where, referring to the matter of tolerances, it is said:

> "On the other hand, **the scientific evidence to support the course of action required of the Secretary by the Court below does not now exist,** and the investigations to obtain it will involve considerable expense and require at least two years after the study is commenced."

Before any definite data as to the toxicity of the new color were available, it became known, in 1956, that the work of determining the "no effect" feeding

level of Red 32, including a "sound, factual basis for a safe tolerance for Red 32 on oranges", had already been done by qualified pharmacological experts in the laboratories of Food and Drug Directorate of Canadian Department of National Health and Welfare.

The Canadian research, now discussed, was conducted by Mr. M. G. Allmark, Chief, Pharmacology and Toxicology Section; Dr. W. A. Mannell, of that Section, and Dr. A. C. Grice, Chief, Animal Pathology Section, of the Food and Drug Directorate of the Canadian Department of National Health and Welfare.

Their article entitled: "Part 2: Observations on The Toxicity of FD&C Green No. 2 (Light Green S. F. Yellowish; FD&C Orange No. 2 (Orange SS) and FD&C Red No. 32 (Oil Red XO) In Rats", **was released on January 10, 1956 and published in June, 1956, in** "The Journal of Pharmacy and Pharmacology", Vol. VIII, No. 6, "By Direction of the Council of the Pharmaceutical Society of Great Britain, 17 Bloomsbury Square, London, W.C.I."

(Since the article was dated January 10, 1956, and related to a matter then being pressed by F&DA, there is no reason to assume (since the closest of relations exist between the two bureaus) that Canadian Food and Drug Directorate did not make these data available to U.S. F&DA not later than January 10, 1956. In any event F&DA knew of the existance of incontestable "scientific evidence" in June of 1956.)

A photostat of reprint of that article is in the Appendix (pp. A8-15) and we respectfully request the particular attention of the Court to the graph curves at pp. A-9 and A-11 and to conclusions reached as recited on p. A-15 thereof, under "Summary", which read:

> "1. FD&C Orange No. 2, FD&C Red No. 32 and FD&C Green No. 2, in concentrations of 0.03 per cent (300 p.p.m.) in the diet did not affect

growth, food consumption, or food efficiency in eiher male or female rats."

"2. In groups receiving FD&C Orange No. 2 and FD&C Red No. 32 in concentrations of 0.75 per cent (7500 p.p.m.) and 1.5 per cent. (15,000 p.p.m.) in the diet, there was 100 per cent mortality before the completion of the experiment."

"3" (Omitted. — Relates to FD&C Green No. 2 only)

"4. Haemoglobin production was not affected by 0.03 per cent (300 p.p.m.) in the diet of either FD&C Orange No. 2 or FD&C Red No. 32, but oral doses of 200 and 400 mg/kg. of these two colours caused a decline in haemoglobin values which was significant in both sexes at 20 weeks.***"

"5 The only significant pathology was found in the tests of those rats receiving a dietary level of 3.0 per cent (30,000 p.p.m.) or an oral dosage of 400 mg/kg. of FD&C Red No. 32." (Parenthetical matter supplied in all).

(To ingest, from eating Color Added oranges, the daily oral dosages of 200 and 400 mg/kg of Red 32 given these rats a human would have to eat, daily, 1750 and 3500 Color Added oranges, respectively, peel and all, or drink 5,000 gallons, daily, of the juice therefrom . . . Ill effects are to be expected from feeding levels of 7500 and 15,000 p.p.m.)

The tests ran 66 weeks, — 465 days. (See Table III Ap. A-10) F&DA considered their 173 day tests (JA. 87) ample to offset 1938-1944 tests by F&DA that ran for 64 to 73 months. (JA 85-86). The Canadian report will likely be accepted by everyone in the scientific world except F&DA, who would have this Court believe, two years later, that "the scientific evidence necessary" (to

establish tolerances) "does not now exist." (Petition, p. 16)

The colors having Canadian designations of "Orange I" (U. S. FD&C Orange No. 1) "Orange S.S." (U.S. FD&C Orange No 2) and "Oil Red XO" (U.S. FD&C Red No. 32) (the three colors decertified by the Secretary's Order) had been on the Canadian list of approved colors for some years, and maximum use limits (tolerances) had been established therefor under Canadian Food and Drug Regulation B.06.004, which reads as follows:

> "B.06.004. No person shall sell a food, other than a coal-tar colour, having in it or upon it an added coal-tar colour for which a standard is provided in B.06.001 to B.06.038, if the proportion thereof exceeds one part by weight of coal-tar colour to each thirty-five hundred parts by weight of food, as prepared for consumption according to label directions."

The tolerance thus prescribed is equivalent to 286 parts per million. Those colors were found to be harmless at 300 parts per million (Oranges contain 4 p.p.m.).

The Canadian research work on FD&C Green No. 2, FD&C Orange No. 2 and FD&C Red No. 32 was doubtless a recheck to verify the validity of those tolerances. It was completed in 1955 and, as shown, no adverse results were noted and the colors remained, for some months thereafter, on their list of approved colors.

However, by Canadian Order in Council dated July 26, 1956, the three colors FD&C Orange No. 1, FD&C Orange No. 2 and FD&C Red No. 32 were removed from the approved list, which, of course, means that Florida and Texas Color Added oranges have been excluded from Canadian markets since October 1st, 1956, another serious blow to the industry of those states, flowing from the unlawful action of FD&A.

The only official reason ever stated for the Canadian ban on Red 32 is contained in the following statement made by Hon. Paul Martin, Minister of National Health and Welfare, in the House of Commons, on July 27, 1956, as reported by "Hansard" (Canadian equivalent of our Congressional Record):

> ***"I shall simply say, in addition to what I have already said, that in taking the steps that we did with regard to the particular colour in oranges the ban applies as of August 1. **It was not because we had found dangerous levels of colour in oranges in Canada but because we simply wanted to take a precautionary step.**
>
> "In the regulations under the Food and Drug Act, provision was made for the use of 17 coal-tar colours in foods. In addition **there is a requirement that the maximum amount of colour to be used in any food is limited to one part per 3500 parts of food or approximately 0.03 per cent.** In surveys which have been conducted in the food and drug laboratories of our department, it has been found that this level is reached in only a few foods, and **the level of colour in the majority of foods, where it is used, varies from one to two parts per 100,000 parts of food.** At the time the permitted list of coal-tar colours was established and with the evidence then available as to the safety of their use in foods, no indication of harmful effects was evident. **Moreover, no reports have come to the attention of the food and drug directorate that the ingestion of foods containing any of the colours in amounts permitted in Canada has caused harmful effects in humans.** However, my hon. friend may be assured that this matter will continue to receive the attention of our officials in the food and drug division

in connection with our own work, **along with that particularly carried on in the United States.** (Emphasis Supplied).

It seems apparent from Mr. Martin's remarks that Canada decertified Red 32, as a "precautionary step", on July 26, 1956, after and, probably, because U.S. F&DA had ordered the decertification thereof on November 10, 1955, since he thereafter gave the same colors a clean bill of health in his remarks in Commons where, as will be noted, it was the use thereof on oranges that was in question.

The attention of the Court is also respectfully directed to Mr. Martin's statement that few foods contain the maximum amount of color permitted under Canadian regulations (1:3500 being 286 p.p.m.) that in the majority of colored foods the color content varies from "one to two parts per 100,000", i.e., 10 to 20 p.p.m. (oranges, 4 p.p.m.).

It should be noted, also that Canada has had no trouble in making those determinations as to tolerances for coal-tar colors, when necessary to protect the public health, which F&DA would have the Courts believe is, for them, an impossible task.

In view of the foregoing it is respectfully submitted that Canada has already done the work necessary to prove the harmlessness of Red 32 for use in all foods, and to establish, for U.S. F&DA, "a sound, factual basis for a safe tolerance for Red 32 on oranges," supported by authoritative "scientific evidence."

We regret that the necessity for discussion of these errors in the Secretary's Petition added 13 pages to an already lengthy brief.

The 1953 Tests of Red 32 As Made By F&DA

We comment on these tests here, although not strictly pertinent at this time, only because the Pe-

tition-Brief states conclusions allegedly based thereon as though the same were proven facts (PB 7-9).

These tests (JA 86-93) ran for 173 days only, and are, of course, offered to offset the results of F&DA tests over 64 to 73 months (1938-1944) (R. 85-86) upon which tests the colors was certified as "harmless and suitable for use in food."

The witness for **the color industry** testified (JA 49) that he accepted the "results" of tests made by F&DA, and this has been cited in the Petition (PB 6-7) as though the witness had testified that he accepted "the conclusions attempted to be premised upon the results of tests made by F&DA", — which he did not imply. Such testimony by that witness for **the color industry** is not properly citable as against the citrus industry or this Respondent.

We will not enter into an extensive discussion of the merits of those tests, vulnerable though they are (R. 243-249, 253, 257) but merely call attention of the Court, in passing, to these points only:

(a) In the tests made by F&DA in 1938-1944, the color and feed were administered separately (R. 85) which feedings methods did not create in the dogs an antipathy for their food. In those tests weight losses from higher levels of color dosage were recovered and the animals finished 64 to 73 months of feedings at levels of as high as 20 mg/kg, (800 ppm) and as low as 5 mg/kg (200 ppm) in good condition (JA 85) showing no adverse effects chargeable to color (JA-86).

(2) In the 1953 tests (JA 87) the color dosage was mixed into the feed given the dogs, which would, of course, create an antipathy, even an allergy, as regards that feed, causing the dog to refuse it, when they suffered diarrhea from such feed, as they did (R. 87). All dogs showed "emaciation" (from "slight" to "extreme" 'JA.

92) at the end of these tests — but the Record is significantly silent as to comparative food consumption and weight figures as between dogs receiving colored and uncolored food.

(3) We respectfully request the attention of the Court to these facts in the case of the one dog that died after 173 days on a diet containing color at 100 ppm., having lost 60% of its body weight and showing "dehydration" (JA 87-89) indicating a refusal of both food and water at the end:

(a) This dog's test was the basis for the Secretary's "Conclusion" No. "4"; "No safe level of administration was found even in test animals for FD&C Red No. 32."

(b) This dog was first put on a diet containing color at 2000 ppm. mixed in its food, and kept thereon until it had lost 24% of its body weight, then with another dog that had lost 19% of its body weight on the same diet, in the same length of time, was put on a color free diet 'for about 10 days', during which time both dogs "regained some weight and improved their physical condition." (JA 87). Then those two dogs, with "two additional dogs", went on this diet containing color at 100 ppm. and at the end of 173 days the first dog died, but the other three dogs "lost some weight but appear in fair condition after nearly 10 months on this level" (JA 87).

(c) These results prompt a question as to why the Secretary bases his above quoted conclusion on the alleged effect on the one dog that died, instead of on the three that tolerated the colored food.

(d) In the absence of comparative figures for food consumption and weight as between dogs on colored and uncolored food, it is impossible for anyone to say whether the adverse effects resulted from refusal of the colored food because (a) it was (1) unpalatable, or (2) induced illness, or (b) were due to an acute allergy developed from

feeding color at the 2000 ppm. level (almost certainly true of the dog that died) or (c) to actual toxicity of the color. Absent such data as to food eaten, any conclusions based on these tests are sheer guess-work, completely worthless. We could contend, with more logic, that the dog died of starvation, unhurt by the color because he would not eat the food containing it.

(e) The figures for the 4 dogs on a color ration of 400 ppm. mixed into their feed (JA 87) are contradicted by the Canadian results, before discussed (p. 20-22 supra) and of the dog on 800 ppm. color feeding in 1938-1944 (JA 85) which strongly indicate that the adverse effects resulted from mixing the colors in the feed, inducing food refusal and consequent malnutrition.

ARGUMENT

Legislative History Of The Act.

We now respectfully submit that the legislative history of the Act makes it very clear (1) that Congress used the word "harmless" in its relative sense and not in any "absolute" sense as contended by F&DA and (2) that the Congress mandatorily required the Secretary to establish tolerances for coal tar colors under Sec. 406 (a)

Prior to the 1938 Act, there was no specific statutory use of the word "harmless". The various regulations relating to coal-tar food colors were issued by F&DA under the general language of the 1906 Act, which provided that food would be deemed to be adulterated.

> "• • if it contains any added poisonous or other added deleterious ingredients which may render such article injurious to health." (F&D Act of 1906; Sec. 7, 34 Stat. 769) (Emphasis supplied.

However, use of the word "harmless", in the regu-

lation of coal-tar food colors, goes back to the first coal tar color regulations ever issued on such colors under authority of the 1906 F&D Act, being Regulation 12 and 13, Bureau of Chemistry, 1907, which were reissued, in 1927, as Regulation 13, reading:

> "(a) Only **harmless** colors and **harmless** preservatives may be used in articles of food." (originally Reg. 12).
>
> "(b) A color, preservative, or other substance, even though **harmless**, shall not be used in the preparation of any food in a manner whereby damage or inferiority is concealed." (originally Reg. 13). (Emphasis ours).

The same or equivalent language was carried forward in reissues of such regulations and remained in effect (See Dunn. p. 1348) until the 1938 Act was enacted, when the word "harmless" was merely transplanted into the Act, in Subsection 406 (b), reading:

> "(b) The Secretary shall promulgate regulations providing for the listing of coal-tar colors which are **harmless** and suitable for use in food and for the certification of batches of such colors, with or without **harmless diluents.**" (Emphasis ours).

The purpose and intent of the Congress in enacting section 406 (b) was stated in clear cut and direct terms. From the first hearing on the bill S-1944 (73rd Congress, 1st Session, 1933, see Dunn, Ap. B, p. 1066) until the final mention of the section in the House Report on Bill S-5 as enacted (75th Congress, 3d Session, 1938, see Dunn, p. 820) that purpose and intent was emphasized repeatedly, as being:

> **"This continues in effect a system of certification which has been followed almost from the beginning of the enforcement of the old food and**

drug law" • • •,. (Dunn, p. 820, emphasis ours).

When read in the light of that statement, there is not a word in the legislative history of the Act which supports the contention of F&DA herein that the Congress intended to limit certification of coal-tar food colors to those that were "harmless" in the absolute sense of that word. Until at least October 13, 1952 (R. 72) F&DA were statedly of the same conviction.

Since Orange 1, decertified by the order appealed from, and Yellow OB (FD&C Yellow No. 4) and Yellow AB (FD&C Yellow No. 3) (now sought to be decertified per "Proposed Rule Making" published in Federal Register for May 4th, 1957, p. 3173), are three of the colors certified in those early days, it is apparent that the word "harmless" was always used in its "relative" sense, since certification would have been prohibited if the word "harmless" had been used in its "absolute" sense.

Since five years have elapsed since F&DA made its initial attempt in 1953 to construe the word "harmless" in an "absolute" sense, rather than the "relative" sense theretofore followed, and since 12 coal-tar colors, all containing such poisons, are still on the certified list and unchallenged as to their "harmlessness", it follows that F&DA is still construing the word "harmless" in its "relative" sense insofar as those 12 coal-tar colors are concerned.

We now further respectfully submit that, specifically, the last amendments to Sec. 402 (c), 406 (a) and 406 (b), prior to enactment of the Act, make it very clear that each of those amendments were enacted pursuant to a very evident purpose and intent of the Congress to insure the continued use of coal-tar colors for coloring citrus fruit.

The pertinent parts of the bill "Senate 5 — 75th

Congress" as it passed the Senate on March 9, 1937, (Dunn, p. 746) read as follows:

Sec. 11 (enacted as section 402) then read:

"Sec. 11. A food shall be deemed to be adulterated;

"(c) If it contains a coal tar color other than one from a batch that has been certified in accordance with regulations as provided by Section 15." (Dunn 782).

Sec. 15 (enacted as Sec. 406) then read:

"Sec. 15 (a) Any contaminating, poisonous, or deleterious substance added to any food, except when such substance is required in the production thereof or cannot be avoided by good manufacturing practice, shall be deemed to be unsafe for purpose of the application of section 11 (a), but when such substance is so required or cannot be so avoided, the Secretary **is authorized** to promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of the public health. • • • .

"(b) The Secretary **is hereby authorized** to promulgate regulations for the certification of coal tar colors which are harmless and suitable for use in foods." (Dunn, p. 785). (Emphasis ours)

The Bill went to the House Committee on Interstate and Foreign Commerce on March 10, 1937, where it remained until August 20th, 1937, when that Committee presented to the House a revised bill (Dunn, p. 751) arrived at by striking everything in the Bill as passed by the Senate except the Title and enacting clause and inserting a House Committee draft.

We find these amendments in this new House draft of the bill, reported on August 20th, 1937, in the sections here concerned:

"Sec. 402. A food shall be deemed to be adulterated—

"(c) If it **bears or** contains a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by section 406: **Provided, that this paragraph shall not apply to citrus fruit bearing or containing a coal-tar color if application for listing of such color has been made under this act and such application has not been acted on by the Secretary, if such color was commonly used prior to the enactment of this act for the purpose of coloring citrus fruit."** (Emphasized matter is amendment concerned).

"Sec. 406 (a) Any poisonous or deleterious substance added to any food, except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice shall be deemed to be unsafe for purposes of the application of **clause (2) of** section 402 (a); but when such substance is so required or cannot be so avoided, the Secretary **shall** promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health, and any quantity exceeding the limits so fixed shall also be deemed to be unsafe for the purpose of the application of **clause** 2 of Sec. 402 (a). **While such a regulation is in effect, limiting the quantity of any such substance in the case of any food, such food shall not, by reason of bearing or containing any added amount of such substance, be considered to be adulterated within the meaning of clause (1) of Sec. 402 (a)** * * *". (Emphasized matter indicates amendment concerned).

"(b) The Secretary **shall** promulgate regu-

lations providing for the listing of coal tar colors that are harmless and suitable for use in food and for the certification of batches of such colors, with or without harmless diluents." (Emphasized matter indicates amendment concerned).

The purpose and intent of the Congress in adding the "proviso" clause to Sec. 402 (c) is crystal clear. The language used is susceptible of but one interpretation — that coal-tar colors were then being used to color citrus fruit, which practice enjoyed Congressional approval; that application for certification of a color so used had been made but had not been acted upon by the Secretary; that to the end that such coloring practice be not stopped or interfered with by the failure or refusal of a Secretary to certify needed colors, Congress was granting special authority for the continued use of that color until the application for certification thereof had been acted upon by the Secretary.

When the corollary amendments to Section 406 are considered in the light of the addition of that "proviso" amendment to Section 402 (c), the purpose and intent of the Congress in enacting those amendments is likewise crystal clear.

As admitted by the Secretary's petition (PB. 19, lines 7-9 of designated par. "A", and cited authorities) Congress was fully informed and advised that: "Coal tar colors have always been recognized as having potentialities of danger." Those coal-tar colors were known to contain small amounts of arsenic and lead, together with other deleterious substances produced by side reactions during manufacture (see F&DA Coal-Tar Color Regulations, p. 46-47).

Coal-tar colors containing such poisonous or deleterious substances were, therefore, clearly within the interdiction of section 402 (a) unless tolerances were prescribed therefor. So long as the statutory power to

fix tolerances and certify colors was permissive or discretionary with the Secretary, the use of coal-tar colors for the coloring of citrus fruits could be stopped or interfered with by the failure or refusal of a Secretary to establish necessary tolerances therefor, or to certify needed colors.

The Congress, therefore, pursuant to its purpose and intent, so clearly evidenced by the amendment to section 402 (c), to insure the continued use of coal-tar colors for coloring citrus fruit, amended Section 406 (a) by changing the permissive "the Secretary is authorized" to the mandatory "the Secretary **shall"** and by spelling out the exemption accorded to foods containing such tolerated amounts of deleterious substances.

Pursuant to the same intent, Congress also amended Section 406 (b) by again changing the permissive "the Secretary is hereby authorized" to the mandatory "the Secretary **shall".**

That the amendments to Sections 402 (c) and 406 (b) are of the same origin and purpose is further evidenced by the fact that the proviso amendment to section 402 (c) and section 406 (b) both refer to the "listing" of certifiable colors, "listing" being a word never before used in the proposed legislation.

It is further to be noted that nowhere in the Act did Congress mention a specific food by name, except in the "proviso" amendment to Section 402 (c) re coloring of citrus fruits, which is indicative of the importance attached thereto by the Congress.

Although these amendments were of decided importance, especially to F&DA, Dunn reports no reference whatever to those amendments in any Report or Debate on the Act. The majority Report to the House (Dunn, p. 819-820) and the Minority Report (Dunn, 834) are silent thereon, and there is no mention thereof in the

prolonged debate in the House (Dunn, 840-963) nor, the Senate having refused to agree to another House amendment, in the Conference Report and statement in the House (Dunn, 970-996). There was no debate in the Senate on either the House re-write or the conference report.

It seems obvious, therefore, that the amendments were accepted as non-controversial by the Congress, and were so enacted. The reason for the lack of controversy will be found at R. 227-228.

We will now discuss the four questions suggested:

(1) **Whether there is any basic conflict between the decision of the Circuit Court of the Second Circuit and the decision of the Circuit Court of the Fifth Circuit.**

We now respectfully show to this Court that there is no basic conflict between the decision of the Second Circuit Court and the decision of the Fifth Circuit Court that would warrant review by this Court, because, first:

(A) **The parties were not the same.**

(B) **The record was not the same.** The record before the Second Circuit Court consisted of no more than:

(1) Notice of hearing set for January 19, 1954 (R. 52 herein);

(2) Excerpts from testimony and exhibits introduced at that hearing;

(3) Notice of Proposed Rule Making, issued in December, 1954 (R. 53);

(4) Exceptions thereto of Coal-Tar Color Industry Committee (R.82);

(5) Secretary's Final Order of November 10, 1955 (R. 281-282);

(6) Coal-Tar: Industry petition to reopen Proceedings (R. 259);

(7) Order denying that Petition (R. 262).

The record before the Second Circuit Court did not contain the Exceptions and arguments thereon as filed by the Florida and Texas Citrus Industry (R. 158-207 herein) nor those of this Respondent (R. 209-259 herein), nor those of four other parties to the Department proceedings. The Second Circuit Court, therefore, had before it a case that was related to the instant case, but as to which the record was fragmentary and misleading, containing but few facts as to the issue before the Fifth Circuit Court.

Moreover, the record before the Second Circuit Court contained no information whatever as to the use of Red 32 on oranges save the analyses of amount of color deposited in the peel of an orange and in certain by products (herein at JA 44-45).

(C) The issues were not the same.

In the Second Circuit Court the issue was whether, on the abbreviated record before that Court, the Secreary's Order, which delisted three colors (Orange 1, Orange 2, and Red 32) prohibiting their general use in **all** foods and **all** drugs taken internally, should be sustained. The question of whether an exception might be made, permitting the use of Red 32 on oranges only (the issue here) was not before that Court, yet the Court said (A-7) that the coloring of oranges presented a different problem.

The issue before the Fifth Circuit Court was whether, on a more complete record, and in view of the precise data presented as to amounts of color used in or on oranges and in by-products thereof, and other pertinent data not before the Second Circuit Court, the facts and the law warranted an exception, **under** (but not contrary to) the decision of the Second Circuit Court, so as to permit the continued use of Red 32 for no other pur-

pose save coloring the peel of oranges, where, as was admitted by F&DA, such use poses no danger whatever to public health.

The Fifth Circuit Court decision did not imply that the decision of Second Circuit Court was in error. Instead, the validity of that decision, on the broad general question before it, was explicitly concurred in by the Fifth Circuit Court. That Court, on a better record, merely settled a point (tolerances) which the Second Circuit Court did not see fit to pass upon.

In our further argument we will discuss the three questions presented to the Fifth Circuit Court and demonstrate that the Fifth Circuit Court was correct in deciding these questions and that, in deciding the questions, the Fifth Circuit Court expressly held that it was not deciding said questions in conflict with the Second Circuit Court but, on the basis of the facts before the Fifth Circuit Court, provided for certain exceptions to the general rule established by the Second Circuit Court.

We will now proceed with argument on the three questions presented to the Fifth Circuit and, in our argument on these three questions, will consistently show that there is no basic conflict between the decisions of the two Circuit Courts.

(2) Whether the Circuit Court, Fifth Circuit, erred in holding that Red 32 is "harmless and suitable for use in foods" for coloring of oranges only, within the contemplation of the Food, Drug and Cosmetic Act.

The fundamental question before both the Second Circuit Court and the Fifth Circuit Court was the purpose, meaning and intent of Congress in the use of the word "harmless" in Section 406 (b) of the Act.

In both lower Courts the appellants contended

that the word "harmless" was to be construed in a "relative" sense and in both cases the Secretary contended that the word "harmless" was to be construed in its "absolute" sense.

Both Courts devoted a considerable portion of their respective opinions to this point.

On this point the **Second Circuit Court** said:

> "Petitioners argue that the 1938 amendment, insofar as those sections are concerned, amounts to nothing more than legislative recognition of existing practice and procedure; that the word 'harmless' must be equated to 'added poisonous or other added deleterious ingredients which may render such article injurious to health' and that these words must be given the meaning assigned to them in **Wood Mfg. Co. v. United States**, 286 Fed 84 (7th Cir. 1923). The **Wood** case adopted a standard of relativity and held that an infinitesimal quantity of arsenic in a coal-tar color was not a poisonous or deleterious substance, injurious to health as ordinarily used, and that the Government was required to prove that the substance was in fact injurious as used. Respondent, on the other hand, urges that the use of a different word — 'harmless' — instead of the more familiar statutory language is evidence of Congressional intent to provide an absolute standard. **We are unable to agree with either of these interpretations.** (Emphasis ours)

The Second Circuit Court decision goes on to state that because Congress, in the Act, dealt separately with (a) poisons inherent in food and (b) poisons added to food, this indicated Congressional discontent with the **Wood** case, and

> **"a return to the principles enunciated by the Supreme Court in United States v. Lexington Mill**

and Elevator Company (232 U.S. 399) wherein it was said:

> "It is not required that the article of food containing added poisonous or other added deleterious ingredients must affect the public health, and it is not incumbent upon the Government in order to make out a case to establish that fact. The act has placed upon the Government the burden of estabilshing * * * that the added poisonous or deleterious substances must be such as may render such aricle injurious to health.
>
> ***In thus describing the offense Congress doubtless took into consideration that flour may be used in many ways, in bread, cake, gravy, broth, etc. It may be consumed, when prepared as a food, by the strong and the weak, the young and the old, the well and the sick; and it is intended that if any flour, because of any added poisonous or deleterious ingredient, may possibly injure the health of any of these, it shall come within the ban of the statute. **If it cannot by any possibility, when the facts are reasonably considered, injure the health of any consumer, such flour, though having a small addition of poisonous or deleterious ingredients, may not be condemned under this act'**
>
> "By restricting the ordinary usage test to non-added substances, the inference is inescapable that Congress meant to similarly restrict the **Wood** case and to correspondingly restore the doctrine of the **Lexington Mill** case * * *."

In the **Fifth Circuit Court decision,** the Court said:

> "The words 'harm', 'harmful', and 'harmless'

are terms of relation. In this sense they resemble 'wrong' and 'wrongful'. Red 32 is harmless, i.e. not harmful, to all persons under the protection of the Act, while it remains in the vat or vial. An injury must occur before harm results. The color Red 32 becomes harmful, i.e. not harmless, when it is consumed, and then only if consumed in such quantity that injury or harm might result. If there can be a use of the color in such quantities that it can be consumed without risk of injury or harm then, in such quantities, it is harmless. A person is as unharmed after consuming a minute harmless quantity of Red 32 (if such there be) as he would be had he consumed none of it.

"In **United States v. Lexington Mill & Elevator Co.**, supra, the Supreme Court reviewed the condemnation of a lot of flour to which had been added a poisonous ingredient but in a quantity so small that the health of a consumer could not be thereby injured. The statute then provided that an article of food should be deemed to be adulterated if it 'contain any added poisonous or other added deleterious ingredient which may render such article injurious to health'. **It was contended there, as it is contended here, that it is the character — not the quantity — of the added substance which is to determine the case. The contention was rejected. The Court said:**

> **"'If it cannot by any possibility, when the facts are reasonably considered, injure the health of any consumer, such flour, though having a small addition of poisonous or deleterious ingredients, may not be condemned under the act.' 232 U. S. 411.**

"As in the Lexington Mill case, it was held in the Seventh Circuit that 'injurious' is a relative

rather than an absolute term. **W. B. Wood Mfg. Co. v. United States,** 7 Cir. 1923, 286 F. 84. We think 'harmless' is also to be so construed."

Thus the Second Circuit Court and the Fifth Circuit Court, while differing somewhat in their approach, arrived at the same conclusion, both holding that the word "harmless" should be construed in the light of this holding by this Honorable Court:

> "If it cannot by any possibility, **when the facts are reasonably considered,** injure the health of any consumer, such flour, though having a small addition of poisonous or deleterious ingredients, may not be condemned under the Act." **(U.S. v. Lexington Mill** supra) (Emphasis Supplied)

We respectfully inform this Court that this Respondent has never asked more than that F&DA observe those guiding words of this Court, which fairly reflect the intent of the Congress.

We next respectfully submit that since both the Second and Fifth Circuit Courts rejected the Secretary's contention that the word "harmless" must be construed in its absolute sense, and held that, instead, the construction thereof should accord with the rule laid down by this Court in **U.S. v. Lexington Mill & Elevator Co.,** it would appear that the real prayer of the Petition is that this Court overrule (not reconcile) not only the decisions of both the Second and Fifth Circuit Courts, but the cited decision of the Supreme Court as well.

(3) Whether the Circuit Court, Fifth Circuit erred in holding that the Secretary had the authority under the Federal Food, Drug and Cosmetic Act to fix tolerances for use of coal-tar colors on or in specified foods.

The next question that was presented to both the Circuit Courts was the question of whether or not the Secretary had authority to establish tolerances for use of coal-tar colors.

Both courts devoted a considerable portion of their respective opinions to this point.

The **Second Circuit Court** decision, on this point said:

> "**The subsidiary question** raised by the denial of a rehearing, **relating to the Secretary's authority to impose tolerances** under which the colors may continue to be used **need not be answered. All we need decide is whether or not petitioners can require him to establish such tolerances. Under the circumstances disclosed in the record we hold that they have no right to do so.** There are two reasons for this. In the first place there is nothing in the record to indicate how much of these coal-tar colors a human being could ingest over a period of years without any harmful effects, nor did petitioners propose to introduce any. The respondent's conclusion in this connection is as follows:
>
> 'While a safe level of administration to test animals is disclosed by the record in the case of FD&C Orange No. 1, the record also discloses that the color has adverse effects upon man at a level well below the safe level of administration to test animals. The safe level of administration of FD&C Orange No. 2 to test animals is well below the level at which FD&C Orange No. 1 was found safe to test animals. It is therefore, even more toxic than FD&C Orange No. 1. No safe level of administration was found even in test animals for FD&C Red No. 32'.

> "Furthermore, it may be impossible to demonstrate the precise cumulative effect over 20 or 30 years of consumption of specified amounts of color and therefore impossible to prescribe safe tolerances. We think that the Secretary's findings that such tolerances cannot be determined should be accepted and that they are dispositive of the case."

Rather than add four more pages to a too long brief, we respectfully make reference to that part of the Fifth Circuit Court's decision having to do with tolerances, which appears in Appendix to the Secretary's Petition, beginning with first paragraph at top of p. 40 and extending through last complete paragraph on p. 43 thereof.

As shown, the Second Circuit decided only that Petitioners could not require the Secretary to establish tolerances **in that case "under the circumstances disclosed in the record"**, because there is nothing in the record to show the amounts of Red 32 that can be consumed by humans without harmful effect and nothing to show the amounts in different food.

That language does not in anywise imply that in a case where it is shown to the Court (as it was shown in the Fifth Circuit Court) that the amount used to color a specific food is so small as to be harmless in the amount used, but may be harmful when consumed in larger amounts, the Secretary cannot be required to establish a tolerance therefor if necessary in order to protect the public health. Indeed, the Second Circuit Court decision pointed out the difference between a case such as was before that Court, involving, as it did, the use of all colors on or in all articles of food, drugs and cosmetics, and a case where only oranges are concerned, saying:

> "Thus the problem is far different from the one presented recently to Congress when the act was amended to permit the use of Red 32 on orange skins not intended for processing. With only one product contaminated it was not too difficult to argue that such small amounts were involved that a man would have to drink 5000 gallons of orange juice a day before experiencing any adverse effects. Hearings Before the Subcommittee on Interstate and Foreign Commerce, 84th Cong. 2d Sess. at 13 (1956)."

The Secretary admits (under "A", PB. 19) that Congress was informed and advised, as far back as 1933, that "coal-tar colors have always been recognized as having potentialities of danger", but complains:

> "In contrast to the Second Circuit the ruling below does require the Secretary to establish tolerances unless he affirmatively proves that the Court's assumption as to the safety of Red 32 is wrong. In short, the Court below has given its stamp of approval to an acknowledged poison and cast the burden on the Secretary to show that the coloring is not safe for oranges." (PB 15).

We respectfully submit that it is the Statute, (Sec. 402 (c)) and not the Court below, which imposed upon the Secretary the mandatory duty of establishing tolerances for a color which is entirely safe in the amounts and for the purpose used, but may be harmful when used in large quantities. The Fifth Circuit merely applied the Statute as it is written.

It should be noted, in passing, that the Second Circuit Court decision affirmatively discloses that the Court misread Section 402 (c) of the Statute, the Court saying:

"Section 402 (c) (21 U.S.C. 342 (c)) was added to deal specifically with the problem of coal-tar colors. It provides flatly that a food shall be deemed adulterated if it contains a coal-tar color other than one from a batch certified under Sec. 406 (b), ***"

whereas the statute reads "other than one from a batch certified under Section 406" — not 406 (b), or 406 (a), but under 406 in its entirely — not just a part thereof.

Sec. 406 is made up of Secs. 406 (a) **and** 406 (b) and when the Congress said that a color must be from a batch certified under Section **406**, that means of course, **under Subsection 406 (b) and under Subsection 406 (a).**

It seems clear, therefore that the Congress mandatorily required the Secretary to establish tolerances, under Section 406 (a), for coal-tar colors certified under Section 406 (b), if such tolerances are necessary to protect the public health.

Moreover, the Secretary has affirmatively recognized that mandate and the relationship between Sections 406 (a) and 406 (b) **and since enactment of the 1938 Act has exercised, and to this day continues to exercise, his authority to fix tolerances for food colors under the authority of Sec. 406 (a).** He has, since 1940, prescribed the amounts of deadly poisons permissible in coal tar colors intended for use in foods, **using the very language of Section 406 (a),** which prohibits added deleterious substances in food except where necessary in production or impossible to be **"avoided by good manufacturing practice."**

We respectfully call the attention of this Court to the following provisions of F&DA Coal- Tar Color Regulations, Section 135.02 whereof reads, in pertinent part:

"Section 135.02. **General Specifications For Straight Colors."**

No batch of a straight color listed in Section 135.03, 135.04, or 135.05 shall be certified under these regulations **unless—**

"(a) **It is free from all impurities (other than those named in paragraph (b) or in the specifications** set forth in such section for such color) **to the extent that such impurities can be avoided by good manufacturing practice.**

"(b) It conforms to the following specifications:

(1) In the case of a straight color listed in section 135.03—

Lead (as Pb), not more than 0.001 per cent.

Arsenic (As^2O^3), not more than 0.00014 per cent.

Heavy metals (except Pb and As) (by precipitation as sulfides), not more than trace." (Emphasis ours).

Under Sec. 135.03 (pp. 3-8) of those same Coal Tar Color Regulations, under the provisions of tolerances clause (a) above quoted, tolerances are fixed in the specifications for 18 colors (listed as certifiable for use in food, drugs and cosmetics) strictly limiting the permitted maximum amounts of still other deleterious substances, as, for example, in FD&C Red No. 32 (pp. 6-7) which provides:

"FD&C Red No. 32

"Specification

"1-Xylylazo-2-naphthol.

Volatile matter (at 100° C.), not more than 0.5 per cent.

Sulfated ash, not more than 0.3 per cent.

Water soluble matter, not more than 0.3 per cent.

Matter insoluble in carbon tetrachloride, not more than 0.5 per cent.

Xylidine, not more than 0.1 per cent.

beta-Naphthol, not more than 0.05 per cent.

m-Xylidine in xylidine obtained by reduction of the dye, not more than 30.0 per cent.

Pure dyle (as determined by titration with titanium trichloride), not less than 97.0 per cent.

Boiling range of xylidine, obtained by reduction of the dye, 95 per cent between 212-232° C."

Yet, after 19 years of thus observing and invoking the provisions of Section 406 (a), in relation to coal-tar colors certified under 406 (b), F&DA has argued before two Courts of Appeals that F&DA has never seen any connection between the provisions of Sections 406 (a) and 406 (b) of the Act.

Yet, very obviously, the Secretary has always used the word "harmless" in its relative sense, is still so using it and, so long as Secs. 135 02 and 135.03 of F&DA's "Coal-Tar Regulations" remain in effect will continue to so use that word in its relative sense, because, absent such construction, and absent that relationship between Subsections 406 (a) and 406 (b), a coal-tar color containing the tolerated content of lead, arsenate and other heavy metals prohibited by Sec. 406 (a), clause 1, would be completely illegal, because the same could not possibly be "harmless" under F&DA's doctrine of "zero toxicity".

Again, Findings of Fact 10 reads (R. 282):

"10. There was no evidence on which findings could be made concerning how much of the three colors is likely to be ingested by man from his food, drugs and cometics. Some interested

> **persons, taking their own products, attempted to show that the the amounts ingested would be small to the point of insignificance. But those contentions leave aside the occurences of the colors in the products of others, as well as the fact that upon certification of a color the Department has no means of controlling the amounts of colors used in a variety of food, drugs and cosmetics. Nor is there authorty to limit a color, once certified, to a single food — for example, FD&C Red No. 32 for use in color-added oranges.** (R. 2021, 67-68, 98-108; Ex. 8.)" (Emphasis supplied).

We ask that the Court compare that language, written for the Secretary by F&DA, when seeking to avoid the power to fix tolerances for coal-tar colors which they admit are harmless in the amounts used in oranges, with the language used by Mr. W. G. Campbell, Chief of F&DA, when testifying before the Senate Committee on Labor and Commerce on December 7th, 1933, in behalf of Section 10 (a) of Senate Bill 1944, which F&DA vigorously contended for when they **wanted** power to fix tolerences for "added poisons" and "added deleterious substances" in food, as in Section 406 (a) as enacted. Then Mr. Campbell testified:

> "This is an extremely important, in fact, one of the most important provisions of this bill. **It may be impossible to preclude absolutely poisonous ingredients from food. Some of the deleterious ingredients with which we have to deal are to be found universally. But it is important that they not only be kept to such a low limit in each article of food in which they may be found that that article of food itself may not be dangerous to health, but important, furthermore, that the total intake of poisons by the consumer of**

foods from all sources be restricted to an amount which will not be dangerous to health."

• • • •

But, Mr. Chairman, and this is another important argument for this particular paragraph, under the terms of the present law we are able to consider only a single commodity. If that single article of food does not contain poison in excess of the tolerance that has been determined as safe for consumption, it is not in violation of the present law. But suppose that article contains just a little less than the safe tolerance. Multiply that by the number of articles of food also containing traces of added poisons which constitute our daily diet, and you can get some conception of what the general intake of poisonous substances would be.

"Now, while there is an economic need for the use of poisonous sprays, **there is no justification at all for the appearance of those poisonous ingredients in a great many food products."** (Dunn, App. B, pp. 1056 - 1057; Emphasis ours)

Thus, when F&DA, in 1933, was seeking, from the Congress, the power to establish and enforce tolerances on all poisons and deleterious substances, F&DA's argument was that such substances are found in so many foods that the aggregate consumption of such substances could be dangerous to public health, making it imperative that F&DA be empowered to establish and enforce tolerances therefor which would take into account the total of all of such substances that a consumer might ingest in all of his food.

But now, F&DA asserts that it is impossible for it to establish tolerances on coal-tar colors which it concedes are harmless in amounts consumed, because so many foods contain those coal-tar colors.

This self-contradictory contention by F&DA was disposed of by the Fifth Circuit in these words:

> "The Secretary, in his Order, has stated that 'the Department has no means of controlling the amounts of colors used in a variety of foods, drugs and cosmetics'. It is not apparent that this is a problem with respect to other toxic substances which are added to foods, under tolerances fixed by the Secretary and nothing is shown to indicate that it would be a problem in dealing with a coal-tar color." (Petition, p. 42)

Again, at "B"; Page 21, the Petition says:

> "B Even assuming that coal tar colors could come within the scope of the 'tolerances' provision of Section 406 (a), the Fifth Circuit has misinterpreted that section in holding that 'required in the production' means 'required in the production for market' by a particular industry, • • •."

Throughout this litigation F&DA has insisted that oranges are food and the law must be applied to oranges as to any other food, but now it insists that oranges are a thing apart from the general classification of foods and that production ceases when the fruit is ready to harvest.

But Section 406 (a) reads:

> "Any poisonous or deleterious substance **added to any food** except where such substance is **required in the production** thereof **or cannot be avoided by good manufacturing** practice • • •."

If the "production" of oranges ceases when the fruit is ready to harvest, the fruit must still be prepared for consumer consumption and, obviously, the steps comprising the cleaning, polishing, coloring and packing of the fruit in citrus packinghouses must be "manufacturing", and the Congress has found the application of color to be an "economic necessity" to the citrus industry.

Therefore, whether the coloring of oranges is deemed to be a "production" practice or a "manufacturing practice" it is comprehended by the language of the act, which mandatorily requires that "the Secretary **shall**" fix tolerances when necessary for the protection of the public health, i.e., when a color that is harmless as used might be toxic when **used in larger quantities.**

We respectfully submit that, whether the coloring of oranges is a production or manufacturing practice, within the meaning of Section 402 (a), F&DA's contention was decided by the Congress, after a full hearing, when considering H.R. 7732, which became P.L. 672. The House Committee on Interstate and Foreign Commerce (p-2, H.R. Report No. 1982; 84th Congress, 2d Session) found as follows (under "Purpose Of The Bill"):

> "The purpose of the bill, as amended, is to permit the orange industry to continue for a maximum period of 3 years (until March 1, 1959) the long-established practice of artificially coloring with a coal-tar color designated as FD&C Red 32 oranges which are ripe but whose skins do not have the characteristic orange color. The standards of maturity which such oranges must meet are established by the law of the States in which the oranges are grown."
>
> **"This practice has become an economic necessity for a major segment of the orange industry,** since large quantities of oranges grown in Florida and Texas would meet with strong consumer resistance if they were not articially colored."

The Senate Committee on Labor and Welfare (Senate Report 2391, 84th Congress, 2d. Session) used the same identical language at page 1 of that report.

In both Houses the Bill thus reported went on the consent calendar and was passed unanimously, thereby formally approving those reports. We respectfully sub-

mit that this Congressional finding is dispositive of F&DA's stated contention.

In view of the Secretary's "conclusions" 2 in the Final Order (R. 282) and hearing in mind the Secretary's contentions that the word "harmless" must be construed in its absolute sense, and that the Act does not authorize tolerances, it is pertinent to consider:

(1) If the statute does not authorize tolerances, and if there be no relationship between Sections 406 (a) and 406 (b) of the Act, by what authority were tolerances prescribed for poisons and deleterious substances in coal tar colors under Sections 135.02 and 135.03 of Coal Tar Colors Regulations?

(2) If there is no relationship between Sections 406 (a) and 406 (b) of the Act, why do those tolerance regulations for colors certified under Section 406 (b), use the language of Sec. 406 (a) of the Act?

3. Upon what supposed rule of construction does the Secretary rely to support his insistance upon his view that although Sec. 402 (c) requires certification of coal tar colors under "Section 406", in its entirety, such requirement applies to Sec. 406 (b) only and does not in anywise refer to Section 406 (a)?

(4) Whether the Circuit Court, Fifth Circuit, erred in holding that the Secretary had authority under the Federal Food, Drug and Cosmetic Act to limit the use of Red 32 to use in coloring oranges.

This point was not raised in the Second Circuit Court, but was raised by the color manufactures (JA 47) and by this Respondent (R. 237) in the Departmental proceedings and was raised by this Respondent in the Fifth Circuit Court, contesting the statement made by the Secretary (last sentence, Finding of Fact 10, R. 282) which reads:

"Nor is there authority to limit a color, once certified, to a single food — for example, FD&C Red No. 32 for use in color-added oranges."

We respectfully invite the attention of the Court to the following excerpts from F&DA Coal Tar Color Regulations, still in effect:

At. p. 3: Under **"Straight Colors — Food, Drugs and Cosmetics"**

"Section 135.03. List of straight colors, and specifications for their certification for use in foods, drugs and cosmetics:

"(a) A batch of straight color listed herein may be certified, in accordance with the provisions of these regulations, for use in food **(subject to the restrictions prescribed by subsection (c) hereof)** drugs and cosmetics, if such batch conforms to the requirements of section 135.02 and to the specifications herein set forth for such color." (Emphasis supplied).

Then on p. 8, still under Section 135.03, we find "lakes" defined as being:

"Any lake made by extending on a subtratum of alumina, a salt prepared from one of the water soluble straight colors hereinbefore listed in this subsection by combining such color with the basic radicle aluminum or calcium".

Immediately thereafter (p. 8) we find "specifications" for "lakes" and subsection (b) designating any "lake" thus made as being a straight color and stating how each "lake" shall be named.

Then (p. 9) there appears, as subsection (c) of Section 135.03, the restriction mentioned in subsection (a) above quoted:

"c" No lake listed in subsection (a) shall be certified for any use in food **except external appli-**

cation to shell eggs." (Emphasis supplied)

At p. 35-36, under: "Sections 135.06. Mixtures which may be certified", we find:

> "(d) No mixture which contains a lake listed in section 135.03 shall be certified for any use in food except external application to shell eggs."

At. pp. 38-39: "Section 135.09 Certification."

Provides for and authorizes certification "subject to the terms, and conditions and restrictions prescribed by section 135.10"

At. pp. 39-40: "Section 135.10. Limitations of Certificates":

> "(i) If a coal tar color from a batch containing any lake listed in section 135.03 is used in coloring any food except shell eggs, such color so used shall be considered to be from a batch that has not been certified in accordance with these regulations."

At. p. 40-41, under: "Section 135.11. Labeling":

Provides that label for such lakes or diluents thereof shall bear the statement: "Not for use in coloring any food except shell eggs."

Other restrictions on or requirements as to "lakes" formulated pursuant to section 135.03, will be found under "Section 135.08, Requests for certification", in subsection 5, at p. 38; in "Sample Forms" at pp. 49, 50, 51, 52, and in "General labeling requirements for coal-tar colors" at p. 53.

Thus, to provide all needed colors for Easter eggs, F&DA's Coal Tar Color Regulation 135.03, at p. 8, carries a definition of a "lake" that permits the manufacture of "lakes" from any or all of ten water suluble FD&C Colors listed, then provides (Sec. 135 03 (c) p. 9) that no such lake "shall be certified for any use in food except external application to shell egg." Thus F&DA undertakes to do the laboratory work incident to

the certification of ten coal-tar colors **which must not be used for any purpose save to color Easter eggs.** — and to police such use.

In order to so accommodate the coloring of Easter eggs, F&DA's Coal-Tar Color Regulations carry, all told, sixteen items comprising specific regulations, or exceptions to regulations, or restrictions as to regulations.

We respectfully direct the attention of this Court to the fact that F&DA has gone to these e xt r e m e lengths in order to make available for coloring Easter eggs a supply of colors that, quite obviously, are completely unsafe for use in foods.

Moreover, they have done this notwithstanding a fact concerning which any school child who ever colored his own Easter eggs could have informed them — that when the eggs are dropped in the hot, sometimes boiling, dye solution, it is common for one or more of the eggs to crack, when the dye enters and colors the entire white of the egg, which is then eaten.

Moreover, certain of those regulations disclose that it was then contemplated that other food colors might be certified subject to a restriction limiting t h e use thereof to a specific food.

Thus, Section 135.06, subsection (a) (3) at p. 35 provides that a mixture of FD&C colors may be certified, **if**

> "no diluent (***) in such mixture is a non nutritive substance, unless such mixture is for external application to shell eggs, **or for use in coloring a food specified in the request for certification of such batch**."

Then, at Section 135.11, subsection (a) (4), provision is made for a labeling to read: **"Not for use in coloring any food except————"**. This labeling was not intended to be used on colors for Easter Eggs. It provides for labeling some other color, also restricted to use on some

specific food, because, five lines further on, another labeling is called for, to read: "Not for use in coloring any food except shell eggs."

So, all of the colors needed for coloring Easter eggs are certified, although such colors are obviously unsafe for use in foods. Such certification continues, while F&DA insisted before two Circuit Courts and before this Court that, to be certifiable, every coal tar food color must be "harmless" in the absolute sense of the word.

As before stated, this question was not raised or considered in the Second Circuit. This Respondent raised it in his Department pleadings (R. 237) and in the Fifth Circuit case, where that Court held:

> "In the order of the Secretary it is stated that there is no 'authority to limit a color, once certified, to a single food — for example, FD&C Red No. 32 for use in color-added oranges'. * * * In the Food and Drug Administration Regulations promulgated in 1955, a number of coal-tar colors were listed for certification for use in food, drugs and cosmetics. Among those are colors designated as 'lakes'. The regulations provide that 'No lake listed in paragraph (a) of this section shall be certified for any use in food except external application to shell eggs.' We shall not indulge in speculation upon the comparative porosity of egg shell and orange peel. We merely observe that the Secretary restricted the use of a group of coal-tar colors to a single food, and we think he was fully empowered to do so." (Petition, pp.43-44)

The Court is now respectfully referred to the statement of the Chairman of the Certified Color Industry Committee (JA 47) offering, on behalf of that entire industry, to restrict the sale of that color for use in coloring oranges, only, and to this Respondent's request that

the Secretary order that this be done (R. 237) to which the Secretary replied with his "Finding of Fact 10" (R. 282):

> "Nor is there authority to limit a color, once certified, to a single food — for example FD&C Red No. 32 for use in color added oranges."

We respectfully submit that the citrus industry of the United States, to which, as formally found by the Congress, the Color Added process is an "economic necessity", is at least as important as the Easter egg industry, and that the flat refusal of the Secretary to accord to the colors needed for coloring oranges an equality of treatment with Easter Eggs colors, constituted an arbitrary, capricious and discriminatory use of the powers of his office.

Conclusion

We respectfully submit that by the foregoing we have conclusively shown that:

(a) While F&DA have contended in two Circuit Courts, and now contends in this Court, that the word "harmless" must be construed in its absolute sense (as to which both Circuit Courts disagree with F&DA) yet F&DA has from the beginning construed, and continues to construe the word in a relative sense, by certifying coal tar colors which contain small amounts of known deadly poisons, of known cumulative properties, to-wit: arsenic, lead and other poisonous heavy metals, which cannot possibly be "harmless" in the absolute sense of the word, nor could a color containing them be legally certified, unless that word be construed as "harmless in the amounts used."

(b) While F&DA have contended in two Circuit Courts, and now contend in this Court that there is no provision in the statute authorizing tolerances for coal tar colors, and that there is no relationship between sec-

tions 406 (a) and 406 (b) of the Act, yet in Section 135.02, at p. 3 of F&DA Coal Tar Color Regulations, they publish tolerances for poisonous arsenic, lead and heavy metals in all certified coal-tar colors, and, in Section 135.03, publish tolerances for other and various deleterious substances in each of the 15 colors still certified for use in foods, drugs and cosmetics.

We respectfully submit that the language used in Section 135.02 (the last clause whereof is lifted verbatim from Section 406 (a) of the Act, and section 135.03, conclusively proves that the Secretary has had, and since 1940 has exercised, and today still exercises, the power to fix tolerances for poisons and deleterious substances in coal-tar colors. Since 406 (a) is applicable to colors certified under 406 (b) for that purpose, certainly it is applicable for all pertinent purposes, i.e., fixing maximum amounts (tolerances) for use of the colors in foods.

(c) While F&DA contended in the Fifth Circuit (but not in the Second Circuit and not, so far, in this Court) that the Act does not permit the limiting of a color once certified to a particular use "for example, FD&C Red No. 32 for use in color-added oranges", yet, since 1940 the Secretary **has had and has exercised and today is still exercising, the power to limit the use of a particular certified color to the coloring of one specific food;** that not only has the Secretary so limited such use, but has gone infinitely further, by setting up specific provisions permitting certification of coal-tar colors (lakes) which are, quite obviously, wholly unsafe for use in foods generally, in order to insure a supply of certified colors for coloring Easter Eggs, **while insisting that the Act does not permit such limitation as to, "for example, FD&C Red No. 32 for use in Color Added oranges".**

We further respectfully submit that, as to the three questions decided by the Fifth Circuit Court there is no basic conflict between the decision of that Court and

the decision of the Second Circuit Court, because:

As to Question 2: Both Courts, while differing in their approach thereto, definitely held that the word "harmless" must be construed pursuant to the rule laid down by this Court in **U.S. vs. Lexington Mill & Elevator Co.** (232 U.S. 399), hence there can be no basic conflict between the decisions of those Courts on that Question.

As to Question 3: As shown (p. 42 supra) the Second Circuit elected not to pass upon the general authority of the Secretary to fix tolerances for coal-tar colors under the provisions of Subsection 406 (a), but confined itself to a finding that "under the circumstances disclosed in the record" Appellants could not require the Secretary to do so in that case. There cannot, therefore, be any basic conflict between that part of the decision of the Second Circuit Court and the decision of the Fifth Circuit Court, with a complete record before the Court, that the Secretary is required to establish tolerances for coal-tar colors.

As to Question 4: The matter of the power of the Secretary to limit the use of a particular color to the coloring of a single specific food, was not presented to or decided by the Second Circuit Court, hence there is no basic conflict on that Question.

There is no suggestion by the Secretary that the decision of the Fifth Circuit Court is in anywise in conflict with any decision of the Supreme Court, nor does any such conflict exist.

We, therefore, respectfully submit that, for

all of these reasons, the petition for certiorari should be denied.

Respectfully submitted,

Morris E. White
of Counsel for Respondent
Frank R. Schell

J. Lewis Hall,
Tallahassee, Florida
Of Counsel.

CERTIFICATE OF SERVICE

I hereby certify that on this first day of March, A.D. 1958, I have served two copies of the foregoing brief on each of the following persons, by air mail, postage prepaid:

Honorable Marion B. Folsom, Secretary,
Department of Health, Education and Welfare,
Washington, D. C.

Honorable J. Lee Rankin,
The Solicitor General,
Washington, D. C.

Honorable Rufus D. McLean,
Acting Assistant Attorney General,
Washington, D. C.

Honorable Beatrice Rosenberg, Attorney,
Department of Justice,
Washington, D. C.

Honorable William W. Goodrich,
Assistant General Counsel,
Department of Health, Education and Welfare,
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Honorable J. Hardin Peterson,
208 South Tennessee Avenue,
Lakeland, Florida

Morris E. White
Of Counsel For Respondent
Frank R. Schell.

Tampa, Florida
March 1st, 1958.

UNITED STATES COURT OF APPEALS

For the Second Circuit

———:———

No. 361—October Term, 1955

(Argued May 14, 1956 Decided August 10, 1956.)

Docket No. 23983

———:———

The Certified Color Industry Committee, Allied Chemical & Dye Corporation, American Cyanamid Company, Bates Chemical Co., Inc., Dyestuffs and Chemicals, Inc., H. Kohnstamm & Co., Inc., Wm. J. Stange Co., Sterwin Chemical, Inc. and Warner-Jenkinson Mfg. Co.,

Petitioners,

—against—

The Secretary of Health, Education and Welfare, Marion B. Folsom,

Respondent.

———:———

Before:

Medina and Waterman, *Circuit Judges,*
and Murphy, *District Judge.*

———:———

Petitions to review an order of the Secretary of Health, Education and Welfare, made pursuant to 21 U. S. C. A. Sections 346(b), 354, 364 and 371, delisting three coal-tar colors manufactured by petitioners. Order affirmed.

———:———

Cravath, Swaine & Moore, New York City (Albert R. Connelly, and Michael F. Markel, of counsel), *for petitioners.*

Warren Olney III, Asst. Attorney General, John T. Grigsby and Frank J. Kierman, Attorneys, Dept. of Justice (Paul M. Steffy, and William W. Goodrich, of counsel), *for respondent.*

MURPHY, *District Judge:*

These are petitions to review an order of the Secretary of Health, Education and Welfare delisting certain coal-tar colors (FD & C Orange No. 1, Orange No. 2 and Red No. 32) manufactured by petitioners. Prior to this order the dyes in question had been certified since 1939 as "harmless" and placed on the approved list for unrestricted use in foods, drugs and cosmetics. Prompted by hearings before a Select Committee of Congress to Investigate the Use of Chemicals in Foods concerning the toxicity and possible carcinogenicity of coal-tar colors, respondent conducted extensive experimental research with laboratory animals which conclusively showed that the colors in question produced substantial deleterious effects and sometimes death. This information and experimental data was given to petitioners sufficiently in advance of the hearing to permit them to offer contradictory evidence. After the hearing on notice, at which petitioners offered no opposing scientific data, the Secretary found the dyes to be "not harmless and suitable for use in coloring food or for use in coloring drugs or cosmetics intended for other than external application," and ordered that they be deleted from the listing.

This order was made November 10, 1955, effective February 10, 1956. Petitioners filed the instant Petition to Review on February 7, 1956, three days before their time would have expired. On January 27, 1956, only twelve days before, they made a motion before the Secretary to reopen the hearings to receive evidence of the maximum extent to which these colors are used in foods (but not of drugs or cosmetics) under normal conditions of use, which were represented to be far less than the levels of administration causing damage to the test animals. This motion was denied on February 20, 1956, on a number of grounds, viz., (1) as to the color Red 32 (a) because no safe levels were found for animals and (b) this color recently caused 196 persons (adults and children) to become acutely ill after eating popcorn with this color added; (2) man appears to be much more susceptible to color dyes than test animals; (3) the proposed proof was inaccurate and incomplete and did not take into account all uses; (4) the statute did not permit tolerances for toxic colors; (5) although the tests proved the colors toxic they did not establish the extent of toxicity to a certainty so as to permit the establishment of safe tolerance, and (6) the Secretary had no authority to establish tolerances with regard to colors.

Petitioners suggest that the basic question for review is whether the statutory language "harmless and suitable for use" (Federal Food, Drug and Cosmetic Act, Section 406(b), 21 U. S. C. 346(b) is to be interpreted in a absolute sense or in a relative sense meaning "incapable

of producing harm under normal conditions of use." Subsidiary to this, they say, is the question whether the Secretary is authorized to impose limitations or tolerances under which colors may continue to be certified. It is their position that the legislative intent can be found in the prior construction by respondent's predecessors which Congress was aware of since it knew that coal-tar colors were toxic and must have realized that their authorized use would have to have some relation to the quantities used. All of this follows, it is argued, since many substances, e.g., salt and vinegar, are concededly not harmless in an absolute sense. The second string to their bow is the argument that the Secretary should authorize limitations or tolerances for these colors for normal use the same as the Secretary does with regard to poisonous or deleterious substances added to food but which are necessary or unavoidable in good manufacturing practice. (Federal Food, Drug, and Cosmetic Act, Section 406 (a), 21 U. S. C. 346(a).)

We turn to the legislative history of the act in an effort to resolve the question whether "harmless" should be construed in a relative or absolute sense. The 1906 Act provided that food should be deemed adulterated "if it contain(s) any added poisonous or other added deleterious ingredient which may render such article injurious to health." (Food and Drugs Act of 1906, Section 7, 34 Stat. 769.) Although no specific provisions were then enacted dealing with coal-tar colors, the Food and Drug Administration early recognized the necessity of special treament for these dyes. Without express statutory authority it issued regulations to the effect that only harmless colors might be used and proceeded to certify for use only those coal-tar dyes which satisfied its specifications. This practice continued until the act was amended in 1938. Under the amended statutory scheme a food is deemed adulterated, "If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health * * *" (Federal Food, Drug, and Cosmetic Act, Section 402(a), 21 U. S. C. 342(a)). Section 402(c) (21 U. S. C. 342 (c)) was added to deal specifically with the problem of coal-tar colors. It provides flatly that a food shall be deemed adulterated if it contains a coal-tar color other than one from a batch certified under Section 406(b), (21 U. S. C. 346(b). This latter section authorizes the Secretary to "promulgate regulations for the listing of coal-tar colors which are harmless and suitable for use in food, and for the certification of batches of such colors * * *." Section 406(a), (21 U. S. C. 346(a) gives the Secretary permission to set up tolerances for added poisonous or deleterious substances which are required or cannot be avoided by good

manufacturing practice. At least to the extent that the amendment authorized the certification of coal-tar colors, it codified the administrative practice of the past 30 years.[1]

Petitioners argue that the 1938 amendment, insofar as these sections are concerned, amounts to nothing more than legislative recognition of existing practice and procedure; that the word "harmless" must be equated to "added poisonous or other added deleterious ingredient which may render such article injurious to health," and that these words must be given the meaning assigned to them in *Wood Mfg. Co. v. United States*, 286 Fed. 84 (7th Cir. 1923). The *Wood* case adopted a standard of relativity and held that an infinitesimal quantity of arsenic in a coal-tar color was not a poisonous or deleterious substance, injurious to health, as ordinarily used, and that the government was required to prove that the substance was in fact injurious as used. Respondent, on the other hand, urges that the use of a different word—"harmless"—instead of the more familiar statutory language is evidence of Congressional intent to provide an absolute standard. We are unable to agree with either of these interpretations.

However, we do agree that the word "harmless" as used in Section 406(b) must have some relation back to Section 402(a). But the provisions of that section, as amended, are substantially different from those of its predecessor—Section 7 of the 1906 Act. The new provision treats deleterious substances separately depending upon whether they are added to or are an integral part of the food. Thus, if the deleterious substance is inherent in the food there nevertheless is no adulteration if the quantity of the substance used does not *ordinarily* render it injurious to health. But if the complained of ingredient is an added one, then the food is adulterated if the substance *may* render it injurious to health. This, so far as added substances are concerned, would seem to indicate legislative discontent with the *Wood* case, and a return to the principles,

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1. Parenthetically it may be noted that on July 9, 1956, the President signed into law a bill further amending Section 402 by the addition of a provision permitting the use of Red 32 on the skins of oranges not intended for processing, such permission to last only until March 1, 1959 or until another suitable color is listed under Section 406, whichever is sooner. Pub. L. No. 672, 34th Cong., 2nd Sess., Chapter 530 (July 9, 1956). What is significant, however, is the vast difference between the bill as proposed and the bill as passed. The former providd for the promulgation of regulations respecting the listing of coal-tar colors for use on orange skins "which are safe in the manner in which used and suitable for such use." The Secretary objected to this but did not oppose the bill in its *final* form. Hearings Before the Subcommittee on Health and Science of the House Committee on Interstate and Foreign Commerce, 84th Cong., 2nd Sess. at 1-3 (1956).

enunciated by the Supreme Court in *United States* v. *Lexington Mill & Elevator Company*, 232 U. S. 399 (1914), wherein it was said:

> "It is not required that the article of food containing added poisonous or other added deleterious ingredients must affect the public health, and it is not incumbent upon the Government in order to make out a case to establish that fact. The act has placed upon the Government the burden of establishing * * * that the added poisonous or deleterious substances must be such as may render such article injurious to health. The word 'may' is here used in its ordinary and usual signification, there being nothing to show the intention of Congress to affix to it any other meaning. It is, says Webster, 'an auxiliary verb, qualifying the meaning of another verb by expressing ability * * * contingency or liability, or possibility or probability.' In thus describing the offense Congress doubtless took into consideration that flour may be used in many ways, in bread, cake, gravy, broth, etc. It may be consumed, when prepared as a food, by the strong and the weak, the young and the old, the well and the sick; and it is intended that if any flour, because of any added poisonous or deleterious ingredient, may possibly injure the health of any of these, it shall come within the ban of the statute. If it cannot by any possibility, when the facts are reasonably considered, injure the health of any consumer, such flour, though having a small addition of poisonous or deleterious ingredients, may not be condemned under the act" (at p. 411).

By restricting the ordinary usage test to non-added substances, the inference is inescapable that Congress meant to similarly restrict the *Wood* case and to correspondingly restore the doctrine of the *Lexington Mill* case. Definition of "harmless" along these lines can scarcely be considered too strict in view of the stringent provisions relating to coal-tar colors. Section 402 (c) deems food adulterated if it contains such a dye, regardless of whether it could possibly cause any harm, if it does not come from a certified batch.

Thus, the government need not prove that the use of Orange 1 and 2, and Red 32, is in fact injurious to health. It is enough if it shows that such addition "might render the article of food injurious." *United States* v. *Lexington Mill & Elevator Company*, supra, at page 410. This it has done by the overwhelming weight of the evidence. Without analyzing the scientific data in the record, suffice it to say that the uncontradicted testimony shows that the least toxic of the three colors in question had serious immediate effect on human beings and that the overall effect on the laboratory animals by proof on autopsy was alarm-

ing. Consequently, the delisted colors are not "harmless" within the meaning of Section 406(b).

The subsidiary question raised by the denial of a rehearing, relating to the Secretary's authority to impose tolerances under which the colors may continue to be used need not be answered. All we need decide is whether or not petitioners can require him to establish such tolerances. Under the circumstances disclosed in the record we hold that they have no right to do so. There are two reasons for this. In the first place there is nothing in the record to indicate how much of these coal-tar colors a human being could ingest over a period of years without any harmful effects, nor did petitioners propose to introduce any. The respondent's conclusion in this connection is as follows:

> "While a safe level of administration to test animals is disclosed by the record in the case of FD & C Orange No. 1, the record also discloses that the color has adverse effects upon man at a level well below the safe level of administration to test animals. The safe level of administration of FD & C Orange No. 2 to test animal is well below the level at which FD & C Orange No. 1 was found safe to test animals. It is therefore, even more toxic than FD & C Orange No. 1. No safe level of administration was found even in test animals for FD & C Red No. 32."

Furthermore, it may be impossible to demonstrate the precise cumulative effect over 20 or 30 years of consumption of specified amounts of color and therefore impossible to prescribe safe tolerances. We think that the Secretary's findings that such tolerances cannot be determined should be accepted, and that they are dispositive of the case. The colors here involved have been shown to be alarmingly toxic. To be sure, it is not certain that continued consumption at present rates will be harmful to a normal consumer. But it is sufficiently likely to make the Secretary's decision a completely reasonable one. Failure on his part to provide an adequate margin of safety might well constitute an abuse of discretion. Cf. *Atlas Powder Co.* v. *Ewing*, 201 F. 2d 347, 355 (3rd Cir. 1952) cert. den. 345 U. S. 923 (1953). The tests were conducted for the sole purpose of determining whether or not the colors were harmless. Now that their toxicity has been amply demonstrated it would be unconscionable for any court to require the Secretary to permit their use without the clearest and most uncompromising evidence that usage at certain levels was absolutely safe. It must be remembered that while petitioners did nothing to obstruct the accumulation of data on this point they certainly did nothing to advance the cause of science. The industry made no pharmacological investigation of its own after 1938, submitted no evidence and readily accepted the results of the studies made by the Food and Drug Administration.

But quite aside from this lack of any evidence in the record indicating a safe level of consumption, there is, as a practical matter, a far more serious objection to requiring a schedule of tolerances. Relying on Exhibit A to the petition to reopen the hearings it appears that the colors in question are used in cakes, cookies, pies, bread, cheese, ice cream, frankfurters, bologna, spreads, oranges, canned and frozen vegetables, candy, desserts and puddings, soft drinks, condiments, soups, pickles, olives and prepared dishes, as well as in unenumerated drugs and cosmetics. Assuming for the moment that the Secretary could determine that X milligrams of coal-tar color per day could be taken for 25 years with absolute safety—How, considering the vast number of items which contain the dyes and the extremely diverse consumer habits of the American public, could he possibley guard against the ingestion of more than X milligrams per day? The short answer, of course, is that he could not. He has made the following specific finding:

> "There was no evidence on which findings could be made concerning how much of the three colors is likely to be ingested by man from his food, drugs and cosmetics. Some interested persons, taking their own products, attempted to show that the amounts ingested would be small to be the point of insignificance. But those contentions leave aside the occurence of the colors in the products of others, as well as the fact that upon certification of a color the Deparment has no means of controlling the amounts of colors used in a variety of food, drugs, and cosmetics. Nor is there authority to limit a color, once certified, to a single food—for example, FD & C Red No. 32 for use in color-added oranges."

Thus the problem is far different from the one presented recently to Congress when the act was amended to permit the use of Red 32 on orange skins not intended for processing. With only one product contaminated it was not too difficult to argue that such small amounts were involved that a man would have to drink 5000 gallons of orange juice a day before experiencing any adverse effects. Hearings Before the Subcommittee on Health and Science of the House Committee on Interstate and Foreign Commerce, 84th Cong., 2d Sess. at 13 (1956).

In view of the impossibility of controlling the intake of coal-tar colors, even assuming maximum tolerances per item could be established, the Secretary acted within his discretion in refusing to reopen the hearings. Cf. *Federal Security Administrator* v. *Quaker Oats Co.*, 318 U. S. 218 (1943).

Order affirmed.

Reprinted from *The Journal of Pharmacy and Pharmacology*, 1956, 8, pp. 417–424

CHRONIC TOXICITY STUDIES ON FOOD COLOURS

PART II. OBSERVATIONS ON THE TOXICITY OF FD&C GREEN NO. 2 (LIGHT GREEN SF YELLOWISH), FD&C ORANGE NO. 2 (ORANGE SS) AND FD&C RED NO. 32 (OIL RED XO) IN RATS

BY M. G. ALLMARK, H. C. GRICE AND W. A. MANNELL

From the Food and Drug Laboratories, Department of National Health and Welfare, Canada

Received January 10, 1956

THIS paper describes further studies on the chronic toxicity of food colours. In Part I of this series some chronic effects of Oil Yellow AB and OB in rats were reported[1]. It has previously been reported by other workers that some colours belonging to the azo and triphenylmethane classes caused tumours to develop in animals after subcutaneous injections[2,3]. As some of these colours are being used in food it was thought worthwhile to examine them for chronic oral effects in rats. The effects of the oral administration of FD&C Green No. 2, FD&C Orange No. 2 and FD&C Red No. 32 on growth, food consumption, food efficiency, blood hæmoglobin, and on the pathology of a number of organs are presented in this paper.

METHODS

The methods employed were similar to those reported for the two yellow colours[1]. The food colours were incorporated in the laboratory diet in the following concentrations: FD&C Green No. 2, 0·03, 1·5 and 3·0 per cent; FD&C Orange No. 2 and FD&C Red No. 32, 0·03, 0·75 and 1·5 per cent. The rats were approximately five to six weeks of age at the start of the experiment. The animals were kept in groups of two to a cage and were given free access to their respective diets and water. Their body weight and food consumption were recorded weekly. For more accurate evaluation of food consumption it would have been preferable to place only one rat in a cage, but this was not possible. Post-mortem examinations were made where possible on rats which died on test. All surviving rats were killed at the end of the experiments and post-mortem examinations were made. Many of the organs were weighed and prepared for histological examination. As a result of an unfortunate accident at the end of the fourth week to the male rats on a dietary concentration of 1·5 per cent. FD&C Green No. 2, data on these rats are not included.

RESULTS AND DISCUSSION

The Effect on Growth Rate, Food Consumption and Food Efficiency

Growth, food consumption and food efficiency curves for the groups receiving the various dietary concentrations of the three colours are shown in Figures 1 and 2. Growth rate, food consumption and food

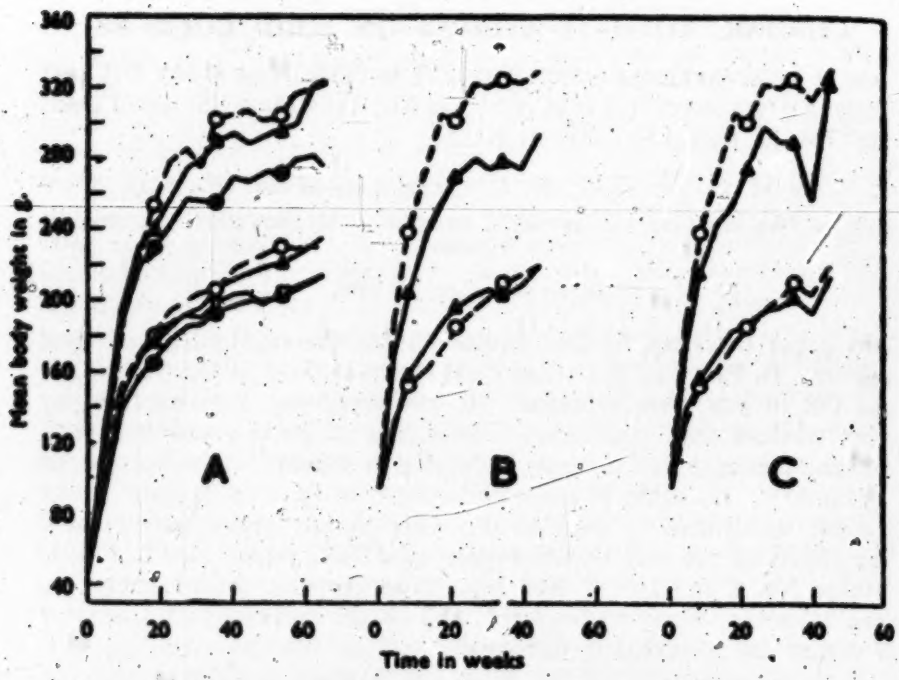


FIG. 1. Growth rate curves for control rats and those receiving the colours. Lower curves are for female rats and upper curves for male rats.

A. FD&C Green No. 2: B. FD&C Orange No. 2: FD&C Red No. 32

○ control; ▲ 0·03 per cent.; ▽ 1·5 per cent.; ● 3·0 per cent.

efficiency were not significantly affected by any of the three colours at the 0·03 per cent dietary level. However, for FD&C Red No. 32 and FD&C Orange No. 2 at the higher concentrations of 0·75 and 1·5 per cent. of the diet, growth rate, food consumption and food efficiency were noticeably affected and all rats in these two groups died before completion of the experiment. For FD&C Green No. 2, two dietary levels, 0·03 and 1·5 per cent. had no effect on growth rate, food consumption or food efficiency, but the 3·0 per cent. level noticeably affected growth rate. This may have been partly due to the amount of food consumed, which was somewhat reduced on this dietary amount. Daily doses of 200 mg./kg. and 400 mg./kg. of FD&C Red No. 32 and FD&C Orange No. 2 for 20 weeks to rats affected growth, food consumption and food efficiency, as shown in Tables I and IV.

The Effect of Mortality

At the end of the test period (65 weeks) the mortality of rats on FD&C Green No. 2 ranged from 52 to 68 per cent. for the respective groups, as shown in Table II. The control group mortality was 68 per cent. The mortality for the respective groups on dietary concentrations of FD&C Green No. 2 was not significantly different from the control. For the other two colours there was 100 per cent. mortality at the 0·75 and

TABLE I

SUMMARY OF DATA ON MORTALITY, FOOD CONSUMPTION AND FOOD EFFICIENCY WHEN FOOD COLOURS WERE GIVEN BY STOMACH TUBE FOR 20 WEEKS

Dose	Sex	No. rats on test	Mortality	Food consumption g./rat/day	Food efficiency g. gain/g. food consumed × 100
Control	M	10	0	13·2	5·2
	F	10	0	11·1	4·7
200 mg./kg./orally/daily FD&C Red No. 2	M	10	6	12·5	2·9
	F	10	0	12·7	3·1
200 mg./kg./orally/daily FD&C Orange No. 2	M	10	6	13·9	3·3
	F	10	2	10·3	4·5
400 mg./kg./orally/daily FD&C Red No. 32	M	10	5	12·1	1·7
	F	10	3	10·1	1·8
400 mg./kg./orally/daily FD&C Orange No. 2	M	10	6	10·3	1·9
	F	10	6	10·0	0·6

1·5 per cent. levels by the time the experiment was ended as shown in Table III. By the end of 20 weeks all the rats on the 1·5 per cent. level of FD&C Red No. 32 had died, and at the end of 40 weeks all the rats on the 0·75 per cent. level had died. It was not possible to make autopsies on all the animals which died during the experiment, but the tissues and organs of many of those dying on the 0·75 and 1·5 per cent. dosage were stained with the colours. The kidneys were soft, dark and swollen. The spleen was enlarged and dark in colour. The picture was one of acute toxæmia.

TABLE II

CUMULATIVE NUMBER OF DEATHS

Concentration of colour in diet %	Sex	No. Rats on test	Time in weeks on test														
			1	3	5	10	15	20	25	30	35	40	45	50	55	60	65
FD&C Green No. 2																	
Control	M	25	1	6	7	8	10	11	12	13	14	14	14	14	14	16	17
	F	25	0	1	1	2	3	3	3	6	6	7	8	8	8	8	10
0·03 per cent.	M	25	0	0	0	1	1	2	4	8	8	8	8	9	11	13	14
	F	25	0	0	0	0	1	4	4	5	6	7	9	11	12	13	13
1·5 per cent.	F	25	0	0	0	0	1	1	2	2	2	3	5	7	13	13	14
3·0 per cent.	M	25	0	0	2	3	3	3	3	4	10	10	11	11	12	13	16
	F	25	0	0	0	2	2	3	4	6	8	8	9	10	10	14	14

The Effect on Organ Weights

Organs of surviving rats were weighed at the termination of the test. The mean weights (in mg./g. of body weight) are shown in Table IV. The mean weights of a number of organs deviated significantly from those of corresponding controls. Heart, liver, spleen, kidneys and testes were the organs chiefly affected. In very few instances where increases or decreases in organ weights occurred was it possible to demonstrate pathological changes; the changes demonstrated in the testes are an exception. In a number of cases the organ weights were about the

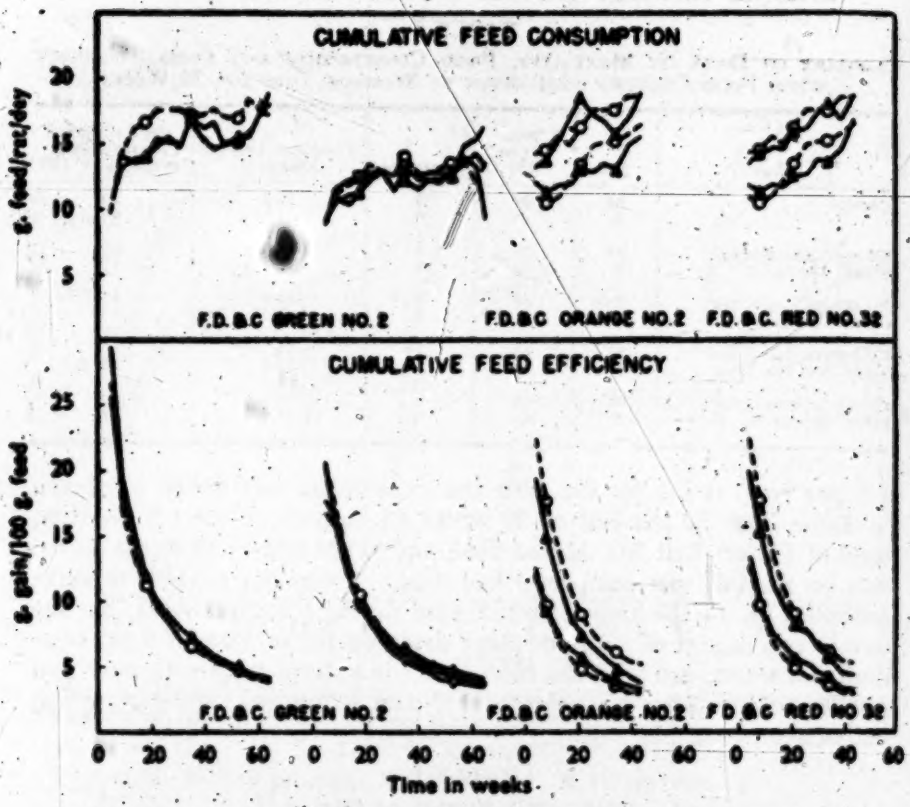


FIG. 2. Food consumption and food efficiency curves for control and test rats, male and female. For FD&C Green No. 2, values for males are shown on the left. For the other two colours, the upper curves represent male rats and the lower curves female rats.

○ Control; ▲ 0·03 per cent., ▽ 1·5 per cent., ● 3·0 per cent.

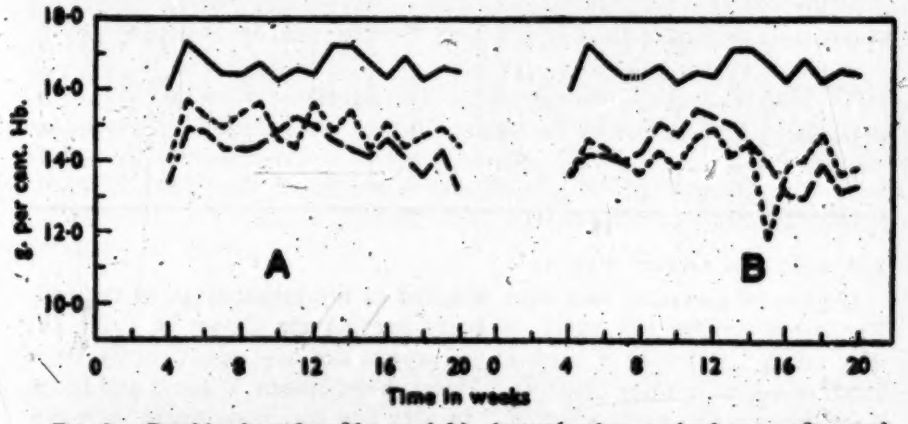


FIG. 3. Combined results of haemoglobin determinations on both sexes of control rats and those given the two colours at different doses. A. F.D.&C. Red No. 32. B. F.D.&C. Orange No. 2.

— Control: - - - 200 mg./kg./rat, oral: — — 400 mg./kg./rat oral.

same as the controls but the body weights of the test animals were less than the controls, suggesting the possible utilization of muscle protein. In other cases the body weights of test and control animals were about the same but the organ weights differed significantly. The changes observed in the organs in these cases appeared like compensatory changes. These results do not demonstrate a correlation of organ weight and the histopathological changes except with the testes.

TABLE III

CUMULATIVE NUMBER OF DEATHS

Concentration of colour in diet	Sex	No. Rats on test	Time in weeks on test											
			2	4	8	12	16	20	24	28	32	36	40	44
FD&C Red No. 32														
Control	M	20	0	2	3	4	5	7	10	11	11	12	13	13
	F	20	0	0	2	2	3	6	7	7	7	7	7	7
0·5 per cent.	M	20	0	0	2	3	3	7	9	9	9	9	16	18
	F	20	0	0	1	1	5	5	6	6	6	6	8	9
0·75 per cent.	M	20	2	3	4	11	15	15	13	16	17	19	20	
	F	20	0	0	0	9	11	13	15	15	15	16	20	
1·5 per cent.	M	20	2	8	11	17	19	20						
	F	20	0	2	10	18	19	20						
FD&C Orange No. 2														
Control	M	20	0	2	3	4	5	7	10	11	11	12	13	13
	F	20	0	0	2	2	3	6	7	7	7	7	7	7
0·5 per cent.	M	20	0	0	1	2	4	6	6	7	8	9	13	13
	F	20	0	0	0	0	1	2	3	4	5	6	7	7
0·75 per cent.	M	20	2	5	10	17	20							
	F	20	3	6	10	17	19	20						
1·5 per cent.	M	20	3	12	17	20								
	F	20	4	10	16	20								

Hæmatology

Hæmoglobin determinations were made weekly for 20 weeks on groups of male and female rats, 10 rats to a group, given daily oral doses of 200 mg./kg. and 400 mg./kg. respectively of FD&C Red No. 32 and FD&C Orange No. 2. A slight modification of the pyridine-hæmochromogen method of Rimington was used[4]. The combined results of these determinations on both sexes are shown in Figure 3, and the mean values of the final determinations are shown in Table IV. The combined blood hæmoglobin values for both sexes show a significant decline in all groups on both colours. This trend was also evident from an examination of the data obtained on each sex.

Blood hæmoglobin values were also determined on the surviving rats from the other experiments. These values, also shown in Table IV, were about the same as those for the controls.

Histopathology

A detailed examination was made of the hæmatoxylin-eosin stained paraffin sections of a number of organs including lung, heart, liver,

TABLE IV

Comprehensive Summary of Observations on Rats fed FD&C Red No. 32, FD&C Orange No. 2 and FD&C Green No. 2

Product	Dosage	No. weeks on test	No. rats surviving / No. rats on test	Mean body weight g. ± s.e.		Mean Hg (g. per cent.) ± s.e.†	Mean organ weight, mg./g. rat ± s.e.					
				Initial	Final		Heart	Liver	Kidneys	Adrenals	Spleen	Testicles
Males												
Control		44	7/20	97·7±5·1	329·1±26·3	15·8±0·29	3·3±0·08	28·6±1·57	6·4±0·07	0·08±0·007	2·4±0·13	8·8±0·35
FD&C Red No. 32	0·03 per cent. of diet	44	2/20	98·4±6·3	330·0± 6·0	16·1±0·75	3·6±0·05	37·0±4·45	7·0±1·20	0·09±0·007	2·6±0·15	8·9±0·73
FD&C Orange No. 2	0·03 per cent. of diet	44	7/20	94·1±5·8	269·4±24·9	15·3±0·50	3·4±0·03	32·5±3·31	7·2±0·13	0·11±0·013	2·4±0·22	8·4±0·63
Control		20	4/10	118·7±5·7	251·0±11·0	17·3±0·40	3·6±0·05	34·9±1·55	7·6±0·25	0·09±0·005	2·5±0·28	9·7±0·38
FD&C Red No. 32	200 mg./kg./day	20	4/10	113·1±4·8	155·0±18·9*	14·1±0·81*	4·6±0·35*	38·2±0·95	9·5±1·55	0·15±0·038*	2·9±0·60	9·6±1·32
FD&C Red No. 32	400 mg./kg./day	20	5/10	115·7±6·4	160·2±14·0*	12·8±1·50*	4·7±0·38*	53·1±2·96*	9·6±0·71*	0·13±0·016*	4·5±0·46*	9·6±1·65
FD&C Orange No. 2	200 mg./kg./day	20	4/10	115·9±4·0	200·0±18·6*	14·1±0·40*	4·1±0·32	44·4±4·46	8·8±0·73	0·12±0·014	4·5±0·32*	11·0±0·70
FD&C Orange No. 2	400 mg./kg./day	20	4/10	110·7±4·0	152·8± 8·6*	13·8±0·64*	5·2±0·18*	44·8±1·59*	8·9±0·49	0·12±0·005	5·0±0·14*	12·9±0·47*
Control		65	8/25	45·6±2·7	323·4±20·0	17·2±0·35	3·2±0·11	30·3±1·01	6·2±0·19	0·08±0·008	2·7±0·26	8·6±0·40
FD&C Orange No. 2	0·03 per cent. of diet	65	11/25	45·5±2·7	323·8±10·9	16·6±0·19	3·4±0·07	32·6±0·82	6·1±0·12	0·08±0·004	2·6±0·11	6·5±0·38
FD&C Green No. 2	3·0 per cent. of diet	65	9/25	45·4±2·7	274·0±12·5*	16·0±0·25*	3·4±0·10	34·9±2·14	6·9±0·38	0·09±0·005	2·3±0·15	5·0±0·69*
Females												
Control		44	12/20	91·7±3·5	219·8± 4·9	15·9±0·22	4·1±0·06	35·7±0·80	7·4±0·21	0·21±0·007	3·4±0·36	
FD&C No. 32	0·03 per cent. of diet	44	11/20	91·8±2·7	214·1± 2·9	14·9±0·66	4·2±0·15	39·2±1·38*	8·1±0·27	0·23±0·010	3·9±0·64	
FD&C Orange No. 2	0·03 per cent. of diet	44	11/20	95·1±3·4	219·4± 3·8	15·6±0·22	4·2±0·13	37·8±1·36	7·8±0·18	0·24±0·011	3·6±0·15	
Control		20	9/10	93·0±3·9	166·9± 6·5	15·7±0·65	4·5±0·41	37·5±1·38	8·2±0·45	0·26±0·031	3·1±0·33	
FD&C Red No. 32	200 mg./kg./day	20	10/10	92·3±4·0	147·6± 5·8*	14·7±0·23	4·5±0·18	43·0±1·73	8·7±0·34	0·20±0·004	4·1±0·15*	
FD&C Red No. 32	400 mg./kg./day	20	7/10	91·6±3·5	124·9± 4·6*	13·4±0·45*	5·0±0·18	51·8±1·92*	9·6±0·14	0·16±0·007*	6·5±2·05	
FD&C Orange No. 2	200 mg./kg./day	20	8/10	88·8±3·3	153·6± 3·1	13·7±0·19*	4·3±0·07	40·2±1·34	7·8±0·30	0·17±0·011	5·6±0·27*	
FD&C Orange No. 2	400 mg./kg./day	20	4/10	89·9±4·0	102·8±11·2*	12·9±1·37*	5·0±0·31	55·1±5·14*	9·9±0·43	0·20±0·022	5·3±0·73*	
Control		65	15/25	39·6±2·4	227·9± 3·9	16·0±0·19	4·1±0·07	35·4±0·84	7·0±0·18	0·22±0·008	3·6±0·13	
FD&C Green No. 2	0·03 per cent. of diet	65	11/25	39·4±2·4	236·7± 6·9	16·4±0·30	3·9±0·09	31·9±1·05*	6·6±0·21	0·21±0·011	3·2±0·06*	
FD&C Green No. 2	1·5 per cent. of diet	65	11/25	39·6±2·3	213·6± 8·7	16·1±0·33	3·6±0·06*	24·4±0·39*	6·1±0·13*	0·16±0·017*	2·7±0·20*	
FD&C Green No. 2	3·0 per cent. of diet	65	11/25	39·7±2·4	210·6± 7·3*	16·0±0·21	4·3±0·12	34·9±1·16	7·3±0·17	0·19±0·005*	3·6±0·22	

* significant at P = 0·05

† determination on 5 rats

TABLE V

SUMMARY OF HISTOPATHOLOGICAL FINDINGS

	Control	Control	FD&C Green No. 2	FD&C Orange No. 2	FD&C Red No. 32	Control	Control	FD&C Green No. 2	FD&C Orange No. 2	FD&C Red No. 32	Control	FD&C Green No. 2	Control	FD&C Green No. 2	Control	FD&C Green No. 2	Control	FD&C Orange No. 2	FD&C Red No. 32	Control	FD&C Orange No. 2	FD&C Red No. 32	Control	FD&C Orange No. 2	FD&C Red No. 32	Control	FD&C Orange No. 2	FD&C Red No. 32
Sex	Male					Female					Female		Male		Female		Male			Female			Male			Female		
Dose	0·03 per cent. in diet					0·03 per cent. in diet					1·5 per cent. in diet		3·0 per cent. in diet		3·0 per cent. in diet		200 mg./kg./day			200 mg./kg./day			400 mg./kg./day			400 mg./kg./day		
Number of rats on test	25	20	25	20	20	25	20	25	20	20	25	25	25	25	25	25	10	10	10	10	10	10	10	10	10	10	10	10
Number of survivors	8	7	11	7	2	15	7	12	13	11	15	11	8	9	15	11	4	4	5	9	8	10	4	4	5	9	4	4
Number of rats examined	5	5	6	7	2	4	7	6	11	10	4	6	5	8	6	6	4	4	4	6	8	10	4	4	5	6	4	4
Duration of test-weeks	65	44	65	44	44	65	44	65	44	44	65	65	65	65	65	65	20	20	20	20	20	20	20	20	20	20	20	20
Bladder parasites			3	4	1	1		2	2	3		2		3		1												
Hydronephrosis						2		1	1	1						2					1							
Chronic glomerulonephritis						1															1							
Pyelonephritis																												
Interstitial nephritis																												
Altered spermatogenesis				1										7														
Necrotic casts in testes tubules																												
Ovary fibroma									1					6														
Ovary cystadenoma																												
Perioophoritis																												
Liver necrosis														1		1												
Lung papilloma																												
Purulent pericarditis																												
Laryngeal abscess							1									1												
Acute tracheitis																												

spleen, thyroid, pancreas, stomach, small intestine, kidney, urinary bladder, adrenal, testes, ovaries and thymus. A summary of the findings is given in Table V. There were no consistent histopathological changes observed in the tissues or organs studied that could be attributed to the toxic effects of the colours with the possible exception of testicular change which was observed in animals on the higher dietary concentrations. These findings were particularly noticeable in rats on dietary levels of 3.0 per cent. FD&C Green No. 2 and in those receiving daily oral dosage of 400 mg./kg. of FD&C Red No. 32. On the 3.0 per cent. level of the green colour testicular change was a constant finding. In seven out of eight animals there was tubular atrophy and incomplete spermatogenesis. The change, although constant, was variable in degree. In some testes a few tubules showed complete absence of spermatogenic cells and in others the spermatogenic cells were greatly reduced. Several tubules in each testis contained deep-blue-staining caseous necrotic casts. Remnants of sperm were present in the necrotic debris. The spermatogenic cells and the supporting network of the tubules were undergoing varying degrees of degenerative changes. In some tubules it was apparent that the necrotic casts were being formed from the degenerating cells.

SUMMARY

1. FD&C Orange No. 2, FD&C Red No. 32 and FD&C Green No. 2 in concentrations of 0.03 per cent. in the diet did not affect growth, food consumption or food efficiency in either male or female rats.

2. In groups receiving FD&C Orange No. 2 and FD&C Red No. 32 in concentrations of 0.75 and 1.5 per cent. in the diet, there was 100 per cent. mortality before the completion of the experiment.

3. FD&C Green No. 2 in a concentration of 3.0 per cent. in the diet adversely affected the growth rate which may have been due in part to the amount of food consumed. At the 1.5 per cent. concentration in the diet of female rats no effect on growth rate, food consumption or food efficiency was observed.

4. Haemoglobin production was not affected by 0.03 per cent. in the diet of either FD&C Orange No. 2 or FD&C Red No. 32, but oral doses of 200 and 400 mg./kg. of these two colours caused a decline in haemoglobin values which was significant in both sexes at 20 weeks. Haeoglobin values were not affected by any of the dosage levels of FD&C Green No. 2.

5. The only significant pathology was found in the testes of those rats receiving a dietary level of 3.0 per cent. of FD&C Green No. 2, or an oral dosage of 400 mg./kg. of FD&C Red No. 32.

The authors wish to acknowledge the technical assistance of Miss Elizabeth Carmichael, Miss Elaine Connell and Miss Rita Carioto.

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In the Supreme Court of the United States

October Term, 1957

MARION B. FOLSOM, SECRETARY OF HEALTH, EDUCATION AND WELFARE, PETITIONER

V.

FLORIDA CITRUS EXCHANGE, ET AL, FRANK R. SCHELL

BRIEF OF FLORIDA CITRUS EXCHANGE AND ALL OTHER RESPONDENTS, EXCEPT FRANK R. SCHELL, IN OPPOSITION TO PETITION FOR WRIT OF CERTIORARI

The Florida Citrus Exchange and all other respondents except Frank R. Schell respectfully object to the issuance of writ of certiorari for the reasons set forth in detail later in this brief.

OPINIONS BELOW

The Secretary's Order (R. 281-282) appears in 20 F. R. 8493. The opinions in the Court of Appeals, printed in the Petitioner's Appendix, pp. 25-52, are reported in 246 F.2d 850. There were two cases in the Fifth Circuit, one - Florida Citrus Exchange et al vs. Marion B. Folsom, Secretary of Health, Education and Welfare, and the other - Frank R. Schell vs. Marion B. Folsom, Secretary of Health, Education and Welfare. The argument on the two cases was combined and there was one opinion but two orders, the orders appearing on page 54 of Petitioner's Appendix.

JURISDICTION

The Petitioner invokes the jurisdiction of the Court under the provisions of 28 U. S. C. 1254 (1) and 21 U. S. C. 371 (f) (4). These citations are correct. The Respondents, however, take the position that there is no conflict with the decisions of the two Courts of Appeal and that the Circuit Court of Appeals has not decided the question in a way in conflict with the applicable decisions of the Honorable Supreme Court of the United States and that there is no justification for the review on certiorari of the decisions of the Court of Appeals of the Fifth Circuit.

QUESTIONS PRESENTED

We feel that the questions as set forth on page 2 of the Petition fail to take cognizance of the fact that the questions before the Court to determine were based upon the consideration of the fact that the color was harmless in the manner and quantity as used, and that Section 406(a) also uses the words "or cannot be avoided by good manufacturing practice." With reference to question 4, the question as stated fails to take into consideration the fact that in the opinion of the Court wide discretion was still allowed in the Secretary to determine the tolerances and to make further investigation and conduct hearings. (See the concluding part of the opinion, appearing on page 48 of the Petition)

We submit our view that the questions to be decided on the review could be simply stated as follows:

1. Did the Court of Appeals for the Fifth Circuit commit error in holding that the word "harmless" must be construed in a relative sense and not in an absolute sense and in holding that the Secretary erred in taking FD&C Red No. 32 off of the certified list for use in coloring oranges not for processing and

meeting the proper maturity standards where there is no showing of likelihood of injury to human beings at the ordinary, normal levels of use?

2. Did the Court of Appeals for the Fifth Circuit err when it held that the Secretary has power to certify for a limited use and/or to provide a tolerance and that he erred in entering the order when he construed the Federal Food, Drug and Cosmetic Act as not giving him such powers?

The Court in its opinion appearing on pages 36 and 37 of the Petition states the question as follows:

> "The decision we are to make is whether the Secretary of Health, Education and Welfare is required or permitted to determine if there is a minimum quantity of the coal-tar color designated as FD&C Red No. 32 which can be used in adding color to the skins of mature oranges without danger of imparing the health of those who consume such oranges; and if so required or permitted, and if it be determined that there is such minimum, should the Secretary list and certify such color for such use."

STATUTE INVOLVED

In addition to the portion of the statute set forth in the Petition we set forth herein Section 402(c) as it appears in the Federal Food, Drug and Cosmetics Act at the time of the Secretary's order:

> "Sec. 402(c) If it bears or contains a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by section 346 of this title: PROVIDED, That this paragraph shall not apply to citrus fruit bearing or containing a coal-tar color if application for listing of such color has been made under this chapter and such application has not been acted on by the Secretary if such color was commonly used prior to the enactment

of this chapter for the purpose of coloring citrus fruit;"

The Act was amended by the passage of Public Law 672, 84th Congress, 2nd Session, taking effect July 9, 1956, by adding at the end of Section 402(c) the following as a part thereof:

"PROVIDED FURTHER, That this paragraph shall not apply to oranges meeting minimum maturity standards established by or under the laws of the States in which the oranges were grown and not intended for processing (other than oranges designated by the trade as 'packing house elimination'), the skins of which have been colored at any time prior to March 1, 1959, with the coal-tar color certified prior to the enactment of this proviso as F.D.&C. Red 32, or certified after such enactment as External D.&C. Red 14 in accordance with section 21, Code of Federal Regulations, part 9; AND PROVIDED FURTHER, That the preceding proviso shall have no further effect if prior to March 1, 1959, another coal-tar color suitable for coloring oranges is listed under section 346 of this title." (21 U.S.C. 342).

STATEMENT

The Secretary of Health, Education and Welfare had hearings and issued an order under date of November 10, 1955 removing coal-tar color F.D.&C. Orange No. 1, Orange No. 2 and Red No. 32 from the approved list of harmless colors for the unrestricted use in food, drugs and cosmetics (R. 281). The Certified Color Industry Committee took an appeal to the Second Circuit as to the entire order and the Second Circuit refused to reverse the Secretary. Its opinion appears in 263 Fed. 2d 966.

The Florida Citrus Exchange and a number of growers and packers in the State of Florida and in

the State of Texas took an appeal to the Court of Appeals of the Fifth Circuit in so far as the order affected the use of F.D.&C. Red No. 32 as used in the coloring of mature oranges meeting certain other specifications. Frank Schell also took the review proceedings to the Fifth Circuit. The Fifth Circuit rendered the decision which Petitioner is seeking to review by certiorari. These two cases were briefed separately but argued together and one opinion rendered. This opinion appears on pages 25 et sequor in the Appendix to the Petition. Petition for rehearing en banc was filed by the Secretary (Respondent in the Court below) and denied.

Matters pertinent thereto are as follows:

1. Red 32 was placed on the approved list in 1939 after a public hearing at which its harmlessness was established. The color which was certified as Red 32 had been used for the coloring of oranges prior to the passage of the Federal Food, Drug and Cosmetic Act in 1938. While the Department of Health, Education and Welfare did initiate new studies yet the tests and studies were not to determine whether the color was harmful at the levels as actually used under normal conditions of use and the tests were not made at levels of ordinary conditions of use and the amounts of the color fed to test animals were far in excess of that used in the coloring of oranges (JApp. 25-26, R. 172) and the Secretary found the evidence inadequate to support the findings as to the amount of color likely to be ingested by man from his foods, drugs and cosmetics (R. 282, Finding 10). The amount of dye in parts per million in the coloring of oranges is shown as Exhibit 8 (JApp. 94) and an analysis of this testimony appears on pages 2, 3, 4, 5, 6 and 7 of the Joint Appendix. At the levels fed a man would have to eat from 2250 oranges to 45000 oranges per day (JApp.

204) before he would get enough of the color to show ill effects from the color and could drink 5000 gallons of juice without any ill effects attributable to the color. Nothing new was developed in these hearings that was not known at the time the color was certified in 1939.

Reference is made to possible carcinogenicity as causing investigation. The Commissioner of U. S. Foods & Drug Administration now states no evidence to that effect and action has been misinterpreted.

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The orange is one of the very few fruits which has blossoms, small fruit and fully mature fruit on the tree at the same time; in the Fall until the cool days come a fully ripe and mature fruit may be green on the outside, when cool weather comes the late variety of orange may have a rich color on the outside and not be fully mature inside. Later in the Spring when the chlorophyll (green color) rises in the tree it goes into the leaves and new fruit and likewise goes into the mature and ripe fruit "regreening it," causing it to be green on the outside although it is fully mature and by reason of this it is impossible to sell unless it is colored. Only oranges meeting high standards of maturity may be colored. The use of color does not involve any element of deception as the oranges are marked "color added." Section 402 of the Act specifically prohibits the use of any color to conceal damage or inferiority in a food product F.D.&C. Red No. 32 was the only color used in coloring oranges and was being sold for such purpose only. (Joint Appendix, p. 47) The coloring of mature oranges has long been recognized by the Industry, the Department of Agriculture and the Congress as a

necessary trade practice and an economic necessity, as will be shown with detailed citations in a subsequent section of this brief. The taking of the colors off of the approved list was not because of any harm or claimed harm as used in the coloring of oranges, the Secretary stating:

> "While the scientific evidence so far available does not establish what the lowest safe dosage would be to test animals, neither does it establish a likelihood of injury to man from the use of this color on the exterior of oranges at the levels of use involved.
>
> " . . .
>
> "The evidence so far available does not establish a likelihood of injury to man from the minute amount likely to find its way into the human diet from the consumption of such colored oranges at the level of use involved." (Report of Secretary of Health, Education and Welfare, February 13, 1956—House Hearings on HR 7732, 84th Congress 2d Sess., p. 3).

3. The Petitions to reopen, referred to in paragraph 3, page 8 of the Petition for Certiorari, were overruled on the assumption by the Secretary that he had no right to continue the certification of colors if they were harmful if fed at high levels to test animals, even though the colors were not harmful when used in normal use in limited quantities, and that he had no authority to limit for particular use or to limit the quantities used. It is our position that it was this erroneous construction of the law by the Secretary which caused the order to be entered. There was no testimony in the record as to the amount used in other foods but there was evidence in the record as to the minute quantities used in the coloring of oranges (Exhibit 8, App. 94).

4. The two cases in the Fifth Circuit were consolidated and argued together and the opinion and judg-

ment are set forth in the Petition for Writ of Certiorari. The effect of the decision was that the Secretary should construe the word "harmless," taking into consideration the manner of use and quantity of color and that he had a right to establish tolerances or to certify for limited use. It still leaves the Secretary with wide discretion as to the necessity of the use and the determination of what is safe and harmless as used. (Pet. 47-48)

The decision protects both the public and the Secretary and provides that a determination may be made by the Secretary on his own initiative or upon the petition of any interested parties as to whether coloring is required and, if so, as to whether Red 32 is a harmless coal-tar color for use in coloring oranges and to fix the tolerances, if any, as may be proper for such use. (Pet. top of 47)

5. The introduction of H. R. 7732 was after the Secretary's tentative order had been entered, but before the decision of the Fifth Circuit, and before the Fifth Circuit had granted a stay, but was not passed until after the Secretary's final order. The coloring of oranges was an economic necessity and had long been encouraged by the Department of Agriculture and, not knowing whether the Fifth Circuit would grant a stay, efforts were made through this legislation to continue the use, but as will hereinafter be shown in the argument, it was not intended to limit its use in the event the Court found under the Act that certification could be continued. The words "less toxic" in line 8 of paragraph 5, page 10 of the Secretary's Petition are his conclusion and are not in the bill itself. The hearings show that the report of the Department had not come in until the day the hearings began, and, when informed of the statement of the Department, the proponents of the legislation

agreed to the amendment. The bill, as introduced, appears on page 1 of the hearings before the House Committee and uses the words "more acceptable on the basis of standards set up by the Secretary," etc. (Hearings, House Committee on Interstate and Foreign Commerce on H. R. 7732, 84th Congress, 2d Sess, pp 2-3) This legislation allowed the use of F.D.&C. Red No. 32 for the coloring of oranges meeting certain standards until March 1, 1959, unless prior thereto another coal-tar color suitable for coloring oranges is listed under Section 406. It is made clear that the use could be continued for such purposes if the Court so determined. The Senate Report concludes with the following words:

> "Inasmuch as the judicial proceedings referred to the above have not as yet been concluded, the committee wants to make it clear that if it is finally judicially determined that the Secretary of the Department of Health, Education, and Welfare already has the power to certify F.D.&C. Red No. 32 for use on the exterior of oranges, the instant legislation is not intended to limit or modify that power."
>
> S. Rep. 2391, 84th Congress, 2d Sess., p-3

The primary purpose was to grant a stay for at least three years. Of course, if the Court determined that under the construction of the Act it could certify then the Congress made it clear in its report that it did not intend to limit the Court's decision.

SUMMARY OF ARGUMENT

Answer to Petitioner's Reason for Granting the Writ of Certiorari. The Fifth Circuit case and the Second Circuit case each distinguish the two cases and are not basically in conflict, and the Fifth Circuit case is not contrary to any decision of the Supreme Court of the United States and is correct.

I. There is no basic conflict between the decisions of the Second Circuit and the Fifth Circuit and no need for resolution of any conflict.

II. The decision of the Fifth Circuit is not demonstrably incorrect but is correct and is in accordance with the decisions of the Supreme Court of the United States, the intent of Congress, as shown by the legislative history, the previous administrative determinations and recognized rules for construction of statutes.

ARGUMENT

ANSWER TO PETITIONER'S REASON FOR GRANTING THE WRIT OF CERTIORARI. THE FIFTH CIRCUIT CASE AND THE SECOND CIRCUIT CASE EACH DISTINGUISH THE TWO CASES AND ARE NOT BASICALLY IN CONFLICT, AND THE FIFTH CIRCUIT CASE IS NOT CONTRARY TO ANY DECISION OF THE SUPREME COURT OF THE UNITED STATES AND IS CORRECT.

The Secretary did by his order bar the use of this color and the two other colors from all foods, but he did this on what we claim is the erroneous assumption that he must construe the word "harmless" in an absolute manner, and that he had no right to certify for a particular use and that he had no right to fix tolerances for coal-tar colors.

It will be noted that that portion of 402(c) quoted by Petitioner on page 12 of his petition referred to certification in accordance with regulations as provided by 406 and not just 406(a). Public Law 672, referred to both in the Petitioner's brief and in this brief and shown in Petitioner's brief in note on pages 11 and 12, also refers to Section 406 and not 406(a). We feel that this has a part in showing that it was intended that coal-tar colors should be subject to tol-

erances, that 402 and 406(a) should be construed together and that all of Section 406 and both subsections (a) and (b) should be construed together. This will be developed more in detail in the subsequent argument. The statute, as referred to on page 13 of Petitioner's brief, uses the words "where such substance is required in the production thereof or can not be avoided by good manufacturing practice," and Petitioner complains of the Court's interpretation of this provision. The requirement in production and in good manufacturing practice and the economic necessity of coloring will be developed in subsequent paragraphs. At this time, however, we want specifically to call to the attention of this Honorable Court the fact that the opinion of the Court of Appeals of the Fifth Circuit (Petitioner's Appendix, pp 47 and 48) very carefully provides that "nothing herein or in the judgment of this Court entered pursuant thereto shall restore said coal-tar color to the list of colors which may be certified for unrestricted use" and then provides that it be for the purpose of coloring the skins of mature oranges and the certificate may be limited for use in coloring oranges only and "provided further, that nothing herein or in the judgment of this Court entered pursuant hereto shall be deemed to restrict the Secretary from making further investigations and conducting hearings for a determination of whether the use of Red 32 is required in the production of oranges and to determine the tolerances, if any, that are safe and harmless, as harmless is herein construed and defined." So, the Secretary still has his broad general powers in determining and making his findings under 406(a). He does, however, have a more flexible definition of the word "harmless" and the word is not construed in an absolute manner.

With reference to the position of the Petitioner in the last paragraph on page 13 of the Petition we again respectfully submit that the decision is not erroneous and is in conformity with the previous decisions of this Court. It does not defeat the object of Congress in passing Public Law 672. The report of both the House and the Senate Committees show that prior to the passage of the bill Industry had already begun its studies and both used the words: "the committee received testimony that these studies were well under way and promised to yield good results." (H. Rep. 1982, 84th Congress, 2d Sess, p-3; S. Rep. 2391, 84th Congress, 2d Sess, p-3). This research has been continued with good results. This matter will be developed further in the argument.

Yellow colors, used principally in margarine, are referred to on the same page of the petition. This decision has nothing to do with any yellow color. No yellow colors are involved in either the Second Circuit case or the Fifth Circuit case, the colors delisted being F.D.&C. Orange No. 1, Orange No. 2 and Red No. 32. (See Opinion, page 28 of Petitioner's Appendix) The Fifth Circuit carefully restricts its decision to F.D.&C. Red No. 32 as used in the coloring of mature oranges. The evidence shows that Red 32 was used and sold only for coloring oranges and the Fifth Circuit order so limited it. (Joint App. 47). We do not believe even any dicta affect yellow colors but even if there were any dicta in the case it is well recognized that the Supreme Court of the United States will not grant review by certiorari to correct dictum. We submit that this decision is not erroneous, that it a well worded and considered opinion, and a careful reading of the opinion shows that the Court of Appeals of the Fifth Circuit had a good grasp of the law, and the facts as it applied to oranges.

The reasoning and result of the decision of the Fifth Circuit neither conflict with the decision of the Second Circuit. Both courts pointed out the difference between the two cases, and the decision does not defeat the object of Congress in passing Public Law 672, 84th Congress, 2d session. The decision is in accord with the previous holdings of the Supreme Court of the United States and is good law. (United States vs. Lexington Mill and Elevator Co., 232 U. S. 399, 34 S. Ct. 337, 58 L. Ed 658)

I

THERE IS NO BASIC CONFLICT BETWEEN THE DECISIONS OF THE SECOND CIRCUIT AND OF THE FIFTH CIRCUIT AND NO NEED FOR RESOLUTION OF ANY CONFLICT

A. The Second Circuit (The Certified Color Industry Committee et al v. Secretary of Health, Education and Welfare, Marion B. Folsom, Respondent, 236 F 2d 866) pointed out the difference between the two cases and among other things at page 871 said:

> "Thus the problem is far different from the one presented recently to Congress when the act was amended to permit the use of Red 32 on orange skins not intended for processing. With only one product contaminated it was not too difficult to argue that such small amounts were involved that a man would have to drink 5000 gallons of orange juice a day before experiencing any adverse effects." 236 F 2d 871.

The Court also in that case pointed out there was nothing in the record to indicate how much of the coal-tar colors a human being would ingest nor did the petitioner in that case introduce any evidence as to this. In the Fifth Circuit case, sought to be reviewed here, the record definitely showed the quan-

tities and that it was not harmful in the manner and quantity used. The Second Circuit case dealt with all three colors. The Fifth Circuit case dealt only with one color and its limited use in the coloring of oranges and there is a showing of economic necessity and the use of this color prior to the passage of the Federal Food, Drug and Cosmetic Act. The Fifth Circuit also pointed out the difference between the two cases with these words in its opinion:

> "We are here reviewing the order of the Secretary only with respect to the coal-tar color F.D.&C. Red 32 as used in the coloring of the skins of oranges . . . We are not confronted with the broad questions which were before the Second Circuit in the Certified Color Industry case, supra." (Pet. App. 38)

Both cases followed the Supreme Court of the United States v. Lexington Mill and Elevator Company and both used this quotation therefrom:

> "If it cannot by any possibility, when the facts are reasonably considered, injure the health of any consumer, such flour, though having a small addition of poisonous or deleterious ingredients, may not be condemned under this Act. (232 U. S. 399; 34 S. Ct. 337; 58 L. Ed. 658)

The Second Circuit held that the word "harmless" was not used in an absolute sense. The Second Circuit also stated:

> "However, we do agree that the word 'harmless' as used in 406 (B) has some relation back to 402 (A)."

The Second Circuit used the words "even assuming maximum tolerances could be established." The Fifth Circuit used these words:

> "and provided further, that nothing herein or in the judgment of this Court entered pursuant

> hereto shall be deemed to restrict the Secretary from making further investigations and conducting hearings for a determination of whether the use of Red 32 is required in the production of oranges and to determine the tolerances, if any, that are safe and harmless, as harmless is herein construed and defined."

Thus it will be seen that the Courts themselves in the two Circuits distinguished the issues and there is no such conflict as to be reviewed by certiorari. The Fifth Circuit also pointed out the difference in the cases:

> "The identical issue is not presented and a different principle is involved. In the Second Circuit case three coal-tar colors were involved and the uses were all inclusive" (page 34- Pet. app.)
>
> "The problem we consider is not that which the Second Circuit had and the decision there is, as we hope to show, not in conflict with what we decide here" (Page 35 Pet. App.)

The Fifth Circuit agrees with considerable of the reasoning of the Second Circuit and limited the decision to F.D.&C. Red 32 as used in the coloring of oranges but leaves the matter wide open for the Secretary to determine in what amount the color can be used with safety and so as not to endanger health and to determine the other required elements before fixing such tolerances. The use for the coloring of oranges was recognized by the Congress.

The Petitioner takes the position that the Fifth Circuit casts the burden on the Secretary to show that the color is not safe for oranges. He overlooks the fact that the order clearly allows the Secretary to determine the amount of tolerances. The color was recognized by Congress in the passage of the 1938 Act and Section 402(c) of the Federal Food, Drug and

Cosmetic Act specifically protected the coal-tar color in common use where application had been made for listing and such application had not been acted upon. The color was subsequently in 1939 certified. The practice of coloring is an economic necessity and so recognized by the Congress.

> "This practice has become an economic necessity for a major segment of the orange industry, since large quantities of oranges grown in Florida and Texas would meet with strong consumer resistance if they are not artificially colored."
>
> Sen. Re. 2391, 84th Congress
> 2d Session, Pages 1, 2 and 3

The hearing and various actions taken are controlled by Section 701 (52 Stat 104 - 21 U. S. 301 et sequor) (Section 371 of 21 U. S. C. A.) which provides in part:

> "(e) . . . The Secretary shall base his order only on substantial evidence of record at the hearing and shall set forth as part of the order detailed findings of fact on which the order is based . . ."
>
> "(f) . . . The findings of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive."

They are also controlled by Section 7 of the Administrative Procedure Act (5 U. S. C. A. 1006), which provides in part:

> "In hearings which Section 1003 or 1004 requires to be conducted pursuant to this section . . ."
> ". . .
>
> "(c) . . .Except as statutes otherwise provide the proponent of a rule or order shall have the burden of proof . . ."

The following statements show the views of the Department:

"There is, however, no evidence that in the amounts used and in the manner of use, in the coloring of citrus fruit, the product so colored is not safe for human consumption."

Statement of Honorable George P. Larrick, Commissioner of Food and Drugs, Department of Health, Education and Welfare. (R-38)

Excerpts from his statement made on hearings on H. R. 7732 are as follows:

"As we interpret the law, the certification of coal-tar colors for use in food does not permit fixing a tolerance for harmful colors for use in or on particular foods; but it provides that if coal-tar colors are not harmless they shall not be listed and certified at all.

"The tests of the toxicity of this color which have been made in the laboratories of the Food and Drug Administration were not designed to learn the effect of this color upon human beings when consumed by reason of its use on the skin of oranges and in the minute quantities that may thereby be ingested, but, rather, the tests were made to determine whether the color is harmless for use in foods generally.

". . . .

"While the scientific evidence so far available does not establish what the lowest safe dosage would be to test animals, neither does it establish a likelihood of injury to man from the use of this color on the exterior of oranges at the levels of use involved. This color has been in use for the coloring of oranges since the early 1930's. We have not found evidence, so far at least, that injury to consumers has resulted from the consumption of oranges so colored.

"Considering all of the information so far available - and bearing in mind particularly the min-

ute amount of this dye likely to enter the human diet as a result of its use on oranges - we cannot say that its continued use on oranges, not intended for processing, would pose a hazard to the public health.

". . . when as here there is no present evidence of injury to man from this partciular use of the dye."

Hearings before a subcommittee of the Committee or Interstate and Foreign Commerce, House of Representatives, 84th Congress, Pages 17 and 18.

The official report of the Secretary appearing on pages 2 and 3 of the same hearings are to the same effect, wherein the Secretary states:

". . . neither does it establish a likelihood of injury to man from the use of this color on the exterior of oranges at the levels of use involved."

The color having been certified for approximately 20 years and having been certified as harmless and suitable for use in food, when at the time of certification it was known that coal-tar colors would cause injury when fed at high levels, but there being no showing of any likelihood of injury in the manner and quantity used in coloring oranges, certainly under these conditions there should be substantial evidence before taking the color off the certified list.

B. We respectfully submit there is no such conflict between the two circuits as to require the need for resolution of differences. Petitioner asserts that on account of the decision there is now no reason for the industry to institute studies or to take action and, on the other hand, the scientific evidence to support the course of action required of the Secretary by the Court below does not now exist. We respectfully call the attention of the Court to the Senate Report on H. R.

7732, which became Public Law 672, 84th Congress, 2d Session, wherein the report states the committee received testimony that "these studies are well under way and promise to yield good results." (S. Rep. 2391, 84th Congress, 2d Sess, p-3)

The Department is well aware of considerable research having been done and we understand in view of the factual nature of the statements made in the Petition that the Petitioner has no objection to our answering with a short factual statement. The Industry has expended more than $127,000.00 in research on new colors since the Secretary's order and has developed a new color with ten times the safety factor of F.D.&C. Red 32 and application is being prepared for the certification of this color. However, if the Secretary continues the position that he must construe the word "harmless" in an absolute sense as he as heretofore, then no coal-tar color can be certified. Since the Secretary's decision was made there has been completed a study by the Department of National Health and Welfare of Canada which confirms a level of no-effect in F.D.&C. Red 32. A pertinent portion of the report reading as follows:

> "F.D.&C. Orange No. 2, F.D.&C. Red No. 32, and F.D.&C. Green No. 2 in concentrations of 0.03% in the diet did not affect growth, food consumption, or food efficiency in either male or female rats."
>
> CHRONIC TOXICITY STUDIES ON FOOD COLORS By M. G. Allmark, H. C. Grice, and W. A. Mannell. Food & Drug Laboratories, Dept. of National Health and Welfare, Canada. Journal of Pharmacy & Pharmacology Vol. 8; pages 417-425, June 1956.

This is far in excess of the four parts per million used on the peel in coloring oranges. There is no showing of any likelihood of danger to the public health.

The Petition again refers to the yellow colors. As pointed out frequently in this brief, the Fifth Circuit decision was limited to F.D.&C Red No. 32. If yellow colors previously certified have been or should be taken off the list the facts in these particular proceeding will be subject to review by the aggrieved parties under the provisions of the Act and such proceedings should have been taken within 90 days, and the Fifth Circuit decision does not affect them.

C. We do not feel that it is necessary for the Court to decide whether the question is moot or not because Petitioner has not made sufficient showing to warrant review.

The 90 days for the review of the decision was a review taken by persons adversely affected, namely, the respondents in this case, and we do not feel that the case of Reed vs. Ewing (205 F 2d 630) cited on page 18 of the Petition is applicable to this particular case.

II

THE DECISION OF THE FIFTH CIRCUIT IS NOT DEMONSTRABLY INCORRECT BUT IS CORRECT AND IS IN ACCORDANCE WITH THE DECISIONS OF THE SUPREME COURT OF THE UNITED STATES, THE INTENT OF CONGRESS, AS SHOWN BY THE LEGISLATIVE HISTORY, THE PREVIOUS ADMINISTRATIVE DETERMINATIONS AND RECOGNIZED RULES FOR CONSTRUCTION OF STATUTES

A. The rulings of the Court below are not incorrect. On the contrary, the decision of the Court below is in accordance with the decisions of the United States Supreme Court, the intent of Congress and the previous administration determinations and the recognized rules for construction of statutes. Both circuits

quote from the case of U. S. v. Lexington Mill and Elevator Co. This case went up from the Western District of Missouri to the Eighth Circuit. The Court of Appeals for the Eighth Circuit reversed the District Court and held that the construction of the trial judge was strained and, among other things, said:

> "The trial Judge decided that if the added substance was qualitatively poisonous, although in fact added in such minute quantity as to be non-injurious to health, it still fell under the ban of the statute . . . There is no warrant in the statute for such strained construction. The object of the law was evidently:
>
> (1) To assure to the purchaser that the article was what it purported to be and
>
> (2) To safeguard the public health by prohibiting the inclusion of any foreign ingredients deleterious to health.
>
> (Citing Hall-Baker Grain Company vs. U. S. 198 Fed. 614.)
>
> Lexington Mill and Elevator Co. vs. United States, 202 Fed. 615

Page 621 of the opinion is very enlightening and it shows the fact that poisons in some greater amounts are frequently present in potable water, bacon, ham, fruits, and certain vegetables, etc. It also refers to "the deleterious effect intended to be prevented by the act." This case went to the Supreme Court of the United States and in the opinion the Court upheld the decision of the Circuit Court of Appeals, and among other things, said:

> "It is evident from the charge given and request refused that the trial Court regarded the addition to the flour of any poisonous ingredient as an offense within this statute, no matter how small the quantity and whether the flour might or might not injure the health of the consumer.

> At least such is the purpose of the part of the charge above given and if not correct it was clearly misleading, notwithstanding other parts of the charge seemed to recognize that in order to prove adulteration it is necessary to show the flour would be injurious to health . . . If it cannot by any possibility where the facts are reasonable considered injurious to the health of any consumer, such flour, though having a small addition of poisonous or deleterious ingredient may not be condemned under the act. . ."

At other places in the opinion the Court used the following wording in quoting the Chairman handling the legislation:

> "As to the term 'poisonous,' let me state that everything that contains poison is not poisonous. It depends upon the quantity and the combination. A very large majority of the things consumed by the human family contain, under analysis, some kind of poison, but it depends upon the combination, the chemical relation which it bears to the body in which it exists as to whether or not it is dangerous to take into the human system."
>
> Lexington Mill and Elevator Co., 232 U. S. 399, 58 Law Ed. 658 Page 412 of the Opinion.

While the Wood case was under the old Act, yet it points out certain observations that are pertinent here.

> 'The evidence in the case does not present a disputed issue of fact, but rather a difference between chemists over the meaning of the words "deleterious ingredient, injurious to health.' In recognizing that a small quantity of arsenic is not injurious to health the government acknowledges that this term is a relative one . . . The Congress has not assumed to define with absolute particularity what is or what is not injurious,

and we cannot accept the testimony of the one witness who testified for the government to the effect that the word 'injurious' is an absolute term. . ."

W. B. Wood Manufacturing Company vs. United States, 286 Federal Reporter —Page 86 of the Opinion.

Just as the government wanted the word "poisonous" and the word "injurious" in the Lexington Elevator case to be construed in an absolute rather than a relative sense and in the Wood case wanted to have the word "injurious" so construed, so in this case does the Petitioner seek to have the words "harmless" and "harmful" construed in an absolute sense. The Court of Appeals of the Fifth Circuit followed the example of the U. S. Supreme Court in the Lexington Elevator case, supra, and did not agree with the Secretary as to his construction of the word "harmless." Neither did the Second Circuit agree with his construction of the word "harmless" The Lexington Elevator case was good law then and is still good law today. The use of the word "harmful" or the word "harmless" did not change the criteria.

The word "injure" means to harm (Websters New Twentieth Century Dictionary, 2d E. page 944); to do harm to (Ballantine Law Dictionary, page 650)

The Petitioner states the question of tolerances becomes much different if more than one product is involved. Tolerances far in excess of the amount used on the skin of oranges in coloring are allowed today for residue on apples, pears, cherries and other fruits and vegetables where the peeling is eaten. The Fifth Circuit in its opinion appearing on page 46 of the Petitioners Appendix very sensibly points out:

"The inability to control the quantity used is no different, as we see it, in dealing with the coal-

> tar color than with respect to other toxic or poisonous substances where the Secretary is required to establish tolerances."

Petitioner again refers to margarine and we again respectfully call the attention of the Court to the fact that this color is not used for coloring margarine and the decision of the Fifth Circuit did not deal with the problems relating to margarine.

On page 19 of the Petition Petitioner refers to statements made by Dr. Calvery and Walter G. Campbell. Both of these recognized that the word "harmless" was to be construed in a relative manner and that tolerances were intended to be granted. At the time of the passage of the Act the Honorable Walter G. Campbell, the then Chief of the Food and Drug Administration of the United States Department of Agriculture, testified:

> "There are very few things, as an illustration, in which you will not find contaminating products in some small degree. With our industrial development, it is extremely difficult to acquire absolute purity in the production of our food supply. . .
>
> "Now, under the terms of the present law and under the terms of this measure as I have read it so far, action would be authorized in such cases only when the amount of that added deleterious ingredient was sufficient to injure health. There is a complete exclusion of added deleterious ingredients by this section, except where necessary in the production of the product or where unavoidable. In those instances the poison will be permitted or tolerated in amounts corresponding to the need of using the poison, or its unavoidability, in each particular food. The total of the amount so allocated will not be enough to jeopardize health."

Food and Drug Act - S. 5

Hearings, Committee on Insterstate and Foreign Commerce, House of Representatives, 74th Congress, 1st Session, pp. 59-60, Dunn Food, Drug and Cosmetics Act, p. 1251

He also had testimony on one version of the Senate bill as follows:

"In Section 10 . . . you will find, in the second paragraph of that section . . . that the Secretary is authorized to make regulations, after notice and hearing, for the certification of coal-tar colors which he finds to be harmless for use in food.

"The Chairman: That is not in the law now?

"Mr. Campbell: That is not in the law now.

"The Chairman: It is there by regulation.

"Mr. Campbell: By regulation we have actually done that. After the existing law became effective the then Bureau of Chemistry, in recognition of the impurities to be extensively found in a great many coal-tar colors and the poisonous character of some of the colors themselves, issued regulations designed to assure the manufacturers and other purchasers that the colors used by them would be non-toxic and free from deleterious ingredients. These regulations established the practice of examining and certifying the purity and safety of coal-tar colors as a method for the protection of the public.

"It is desirable that it be continued. In this language we are asking for legislative confirmation of a practice which has existed since 1907."

Hearings before a Subcommittee of the Committee on Commerce, United States Senate, 73 Cong. 2d Sess. on S. 1944 Dec. 7, 1933 (U. S. Government Printing Office, 1934) pp. 28-29

He also in the Senate hearings made the following statement:

> "We find that authority is delegated after appropriate investigation which will result in the determination of pertinent facts to establish by regulation tolerances in food products by added poisons and deleterious ingredients; certificate of coal-tar dyes for food, drugs and cosmetics."
>
> Hearings before subcommittee of the Committee of Commerce, U. S. Senate, 74th Congress, 1st Sess., pp. 358 and 359

On page 96 of the House hearings he referred to the authorization for the establishment of tolerances.

Senator Copeland, a medical doctor who was at that time Chairman of the Senate Committee handling the legislation in the hearings just previously referred to made this statement:

> "So, the Department itself would have to determine whether there was too much of this or that poison in the cosmetic, if there is any there."

The Senate and the House Reports show the recognition of the certification of coal-tar colors and states that legislative sanction is given to the administrative practice of the Department. The final report prior to the conference states:

> "Subsection (b) of this section specifically authorizes the listing of harmless coal-tar colors for use in food and the certification of batches of the listed colors which are found to be sufficiently free from impurities to be safe. This continues in effect a system of certification which has been followed almost from the beginning of the enforcement of the old food and drug law in order to make available to the food manufacturing industries adequate supplies of colors of established safety and purity."

House Rep. No. 2139 (75th Cong., 3d Sess.) 1938

Sen. Rep. No. 361, 74th Cong., 1st Sess. (1935)

This view and construction is borne out by the testimony of Dr. Calvery, then Chief of the Division of Pharmacology, in his testimony on certification of coal-tar colors shortly after the passage of the Food, Drug and Cosmetic Act. (page 233 of the hearings when F.D.&C. Red was certified in 1939)

"Q. 'Are there in your opinion any coal-tar colors that are harmless and suitable for use in all kinds and classes of Foods, Drugs and Cosmetics.'

"A. (Dr. Calvery), 'No, in my opinion there are no coal-tar colors that are harmless and suitable for use in all kinds and classes of Foods, Drugs and Cosmetics'. . ."

Later in the hearings he made the further statement: (page 243 of the hearings)

"Q. 'What do you mean by the terms that you have used, 'harmless and suitable for use'? The use to which the color is to be subjected?'

"A. 'Yes, by harmless and suitable for use for the purposes indicated, we mean that in the concentrations that these substances are used for coloring purposes, it is our opinion that no harm can come from them to the user when used in the concentrations for which they are designed'. . .

"Q. In considering the amount used, does the tinctorial property of these coal-tar colors have some bearing on the amount used?

"A. "Yes, the tinctorial properties of the coal-tar colors is such that when they are used

in foods, drugs and cosmetics they are used in relatively small percentages, and one takes that into consideration when one speaks of the toxicity of these substances assumed as harmless and suitable for use in drugs and cosmetics.". . . .

"Q. "Dr. Calvery, how do you arrive at percentage of color which should be allowed as harmless and suitable for use in foods, drugs and cosmetics?"

"A. "We arrived at the conclusion that we have concerning the use of these from our conferences with the cosmetics, food and drugs manufacturers, and after learning from them what the percentages are which in most cases are a fraction of a per cent, we based our reasoning on that premise. The colors are not certified for use as colors to be consumed as colors. They are certified—at least we are permitting the listing of these for certification—on the basis of the fact that they will be used as we have been told they are being used at the present time, that is, in small percentages." . . .

Hearings U.S.D.A. F.D.&C. Docket No. 4. Feb. 7, 1939, pp. 233 and 243;
Hearings U.S.D.A. Docket F.D.&C. 9, July 1939, Page 63

When we compare this with the testimony of Dr. Vos, Assistant Chief of the Division of Pharmacology of the Food and Drug Administration, the main witness on whose testimony the colors were decertified we will see that there were no new facts brought into the matter and that at the time of certification it is shown that "harmless" was construed by the Department taking into consideration the quantity and manner of use. This is pertinent on the construction of the word "harmless" as well as the right to fix tolerances. The

limitation as to quantity was important. This is only another way of saying tolerances.

Excerpts from Dr. Vos' testimony are as follows:

"Were you using the term 'harmless' then in the absolute sense that each of the colors were capable of producing harm? A. That is correct.

"Q. In that sense, then, is not common salt capable of producing harm? A. Well, I believe in the case of common salt you have to take into consideration the fact that it is essential to live, so that since you can't get along without some salt, I don't think you could ordinarily consider salt harmful.

"Q. Nevertheless, if you took salt in a quantity of two or three ounces, you may get some bad results from salt? A. There would be some adverse effects from two or three ounces of salt, yes. (App. 27-28)

". . .

"Q. Dr. Vos, aren't the amount and method of proposed use of a material necessary data for deciding whether the material is harmless for the use intended?

"The Witness: I would say, yes" (R. 120, App. 32)

". . .

"The Witness: Yes, The amount of the dye, of the color, has to be considered in determining whether or not it is harmless." (R. 120, App. 32)

Again, Dr. Vos, Respondent's expert witness testified:

"Q. Well then, these levels were not specifically related to the levels of these colors as actually used under normal conditions of use? A. No, that was not a part of this.

"Q. Have you any evidence at such levels where the capacity for producing harmful effects was

tested at levels of ordinary conditions of use?

A. I have very little information on the matter of what the customary levels of use are." (App. 25, R. 172)

"Question: Dr. Vos, then you have no evidence as to the capability of producing harmful effects of any of these colors at the level of ordinary use under normal conditions of use, I should say.

Dr. Vos: Without having more thorough information on the actual level of ordinary use, I would hesitate to answer that question.

Question: Well, you have no evidence at levels other than the levels appearing in the exhibits.

Dr. Vos: That appear in the exhibits, that is correct." (R. 172, App. 26)

"Yes, the amount of dye, of the color has to be considered in determining whether or not it is harmless." (R. 120)

"THE WITNESS: I think it is appropriate the method of use should be taken into consideration. The dyes in question are at present being certified for use in foods, drugs, and cosmetics, and the data which we presented in these exhibits have shown that they are not harmless for use in all of those products. As I have pointed out, we have no data as to whether they are or are not harmless for external application." (App. 33-34)

From a technical viewpoint a distinguished food chemist sums matters up with the following statement:

"There is no foundation in toxicology for regarding all substances as either poisonous or deleterious, on the one hand, or safe or harmless, on the other. The optical physicist has his absolute white and absolute black, but there are no absolutes for the toxicologist. 'Toxicity' depends on species,

age, weight, sex, dosage, route of administration, physiological or pathological state, and manifold other factors comprising 'experimental conditions.' Translation of toxicity data into terms of real or potential effects under any given set of circumstances; as for example, the determination of hazard to any particular segment of the population or to the public health generally, involves considerations that go far beyond toxicity effects in laboratory animals."

Oser, CAN A POISON EXIST IN A VACUUM?
A Discussion of Section 406 (a), 8 Food, Drug, Cosmetic Law Journal, 693, 696, (1953).

The best scientific opinion agrees with this position; the Ad Hoc Advisory Committee of the National Academy of Sciences in its report of June '56 pointed out that the certification of a compound as "harmless and suitable for use" in food, etc, is unrealistic unless the level of use is specified, and that under the rigid interpretation of this directive many components of ordinary diet could not be certified and the Food and Drug Administration will be handicapped in setting up sound research programs designed to determine safety of coloring for human use and consumption so long as it is denied authority under the law to specify levels of use.

The Report of the Ad Hoc Advisory Committee of the National Academy of Sciences—National Research Council, Reviewing the Food and Drug Administration Research Program on Coal-tar dyes, June 1956, page 17.

While prior to the 1938 Act coal-tar colors were not mentioned or treated specifically in the Food and Drug legislation they were certified under the regu-

lations of the Food and Drug Administration as will be seen by the testimony of Dr. Campbell hereinbefore referred to and subsequently referred to in Congressional reports.

> Administrative Procedure and Practice in the Department of Agriculture under the Federal Food, Drug and Cosmetic Act of 1938, prepared under the direction of Mastin G. White, Solicitor (1940), p. 65.

Regulation No. 13 entitled COLOR AND PRESERVATIVES, used the words:

> "(a) Only harmless colors and harmless preservatives may be used in articles of food."
>
> Regulations for Enforcement of Federal Food and Drug Act. (S.R.A.F.D. No. 1 issued Nov. 1930)

Regulation 12 also contained the words:

> "Only harmless colors may be used in food products."

The methodology is described as follows:

> "The harmless nature of the color is appraised by a study of the results of (physiological) investigations. To be taken into consideration are the minimum lethel dose, as determined by the experiments, the chronic toxicity as demonstrated by damage to internal organs and growth rate, and the various dermal tests."
>
> Herrick, Food Regulation and Compliance, v. 2, p. 998 (1947)

The testimony showing that there were no known harmless coal-tar colors for all purposes and this having just been stated to the Congress, certainly it would have been futile for Congress to have said that the Secretary shall certify coal-tar colors which are harmless and suitable for use in food unless it was meant

in a relative manner. Any other interpretation would have been absurd. And to have provided as the Congress did in 402(c) to allow the continuation of coal-tar colors unless action was taken on certification and then to decertify the same color 20 years after certification would be to defeat the will of Congress. Certainly it was intended to use the word in a relative manner and to allow tolerances and/or limit certificates for the purpose of protecting the public health. Under the other regulatory portions of the Food and Drug Act the Secretary had broad powers and there was no restriction preventing this.

Petitioner claims that the Fifth Circuit has misinterpreted 406(a) in holding that "required in production" means required in production for market by a particular industry. The principal purpose of producing any agricultural commodity on a large scale is for a market. We have passed the time when a grower merely raises for his own consumption, and the words "production thereof and good manufacturing practice" embrace those things that are necessary to get the product ready to ship.

The record and scientific publications clearly show that in order to market the crop of oranges it is necessary to color. As hereinbefore set forth Congress in its report referred to it as an economic necessity. The following technical and official publications show the necessity:

> "It is well known that citrus fruits grown under certain climatic and cultural conditions may be mature and highly desirable for food while the skin of the fruit is still green in color . . . In general, when it reaches full color on the trees the fruit in this region is characterized by a low acidity, with a comparatively high sugar content, and the overripe fruit is inclined to be insipid in flavor.

It is important then, if this fruit is to be furnished to the consuming public in its most desirable condition for food, that it be harvested before it becomes yellow on the trees . . . It is evident, then, that some method of treating this fruit so that it would assume a rich orange yellow color early in the season, when it is most desirable for food, would be of benefit to the industry and to the consuming public alike."

U. S. D. A. Bulletin No. 1159
August 1923

"Some of the early fall varieties of oranges and grapefruit ripen while the fruit is still green in color . . . There is, therefore, no definite relation between flavor or maturity and the color of the fruit while on the tree. However, there is a very significant relation between the color of the fruit offered for sale and the price it will bring, and citrus fruit producers have always faced the problem of making the color of ripe fruit match its flavor."

U.S.D.A. The Year Book for 1932, pp. 134-137

"It is obvious, then, that treating fruit which is physiologically mature or has reached a stage in its development at which it has high dessert quality, so that it assumes a color or appearance pleasing to the eye and has a higher decorative value, is a legitimate practice in marketing and one which should be encouraged."

U. S. D. A. Bulletin 1367, May 1926, 167

but the decision of the Fifth Circuit still leaves the Secretary power to determine whether the coloring is required in the production of oranges and to determine the tolerances, if any, that are safe and harmless.

Reference to the use and the necessity for the use are a recital of what the Congress had said and was

previously quoted in this brief. The Court is well aware of the many decisions holding that fruit packing houses engaged in the production of goods for commerce and that the packing and wrapping and making ready for market are considered as part of the production. The factual question is left open to the Secretary for determination. So, there is no new rule of law set down nor any misinterpretation of the statutes. We feel the Petitioner has misconstrued the Court's opinion and, as we view it, a reading of the complete decision shows a well reasoned and carefully considered decision.

With reference to certifying for one particular purpose, this is merely one of the methods of limiting the use of a color. The Secretary claimed he did not have that right and the Court of the Fifth Circuit said that he did. This, I understand, will be treated more in detail in Mr. Schell's brief. However, we respectfully call attention to that portion of the Fifth Circuit's decision appearing in the last paragraph on page 43 and the first paragraph on page 44, wherein it showed the certification of a color for coloring eggs. The F.D.&C. Red 32 is an oil soluble color and does not penetrate the rag of the orange, so if a color could be certified for coloring eggs there is on reason why a proper color could not be certified for coloring oranges. The Secretary has likewise certified F.D.&C. Violet No. 1:

> "The amount of color fed the animals in the tests referred to in finding No. 12 was far in excess of the amount that any human might obtain as a result of food colored with F. D. and C. Violet No. 1."
>
> Finding of Fact No. 13, 15 Fed. Reg. 3517, (June 7, 1950)

Certification was made of a color for use by Section 135.1 (CFR) of the regulations and providing a

restricted use providing that it should not authorize the certification of any such color for use in any article which is applied to the area of the eye. There was no specific statutory authorization for this limitation but it was upheld by the Court of Appeals in the Fifth Circuit wherein it said:

> "The statute contemplates that he shall not arbitrarily exercise his power, but shall act only upon a conscientious judgment derived from a consideration of the facts and conditions to which the regulation is to be applied."
>
> Byrd vs. United States, 154 F. 2d 62 (5th Cir. 1946)

We respectfully submit that even in the order under review the Secretary took the colors off of one list and relisted them for external use in cosmetics which is not itself a restricted list. If he can list a color for applying on lips or to skin he can list a color to be used only for applying to the outside of oranges and the Fifth Circuit correctly so held. It is only an additional method of protecting the public health.

Incidentally, while the particular review provision was brought by the Florida and Texas growers and packers, the order does not limit its use in these states and allows the certification "as may be necessary to color the skin of mature oranges."

The Court of Appeals of the Fifth Circuit correctly construed the word "harmless" in a relative sense and not an absolute sense. The decision of the Fifth Circuit is in accordance with the general rules of statutory construction. This Honorable Court laid down certain general rules in the case cited below:

> "It is a familiar rule that a thing may be within the letter of the statute and yet not within the statute, because not within the spirit nor within the intention of its makers.

"This is not the substitution of the will of the Judge for that of the Legislator, for frequently words of a general meaning are used in a statute, words broad enough to include an act in question, and yet a consideration of the whole legislation or the circumstances surrounding its enactment, or the absurd results which follow from giving such broad meaning to the words, makes it unreasonable to believe that the Legislator intended to include the particular Act.

"It is the duty of the Courts under those circumstances to say that however broad the language of the statute may be, the act, although within the letter, is not within the intention of the legislature, and cannot come within the statute."

Holy Trinity Church vs. United States, 145 U. S. 457, 459, 12 Supreme Court 511, 512, 36 Law Ed. 226.

The Circuit Court of Appeals in the Second Circuit in a Food and Drug case, said:

"The general language should not be so construed to ruin a legitimate business and yet remedy none of the evils the statute was designed to remove."

French Silver Dragee Co. v. United States, 179 Federal 824

The Court of Appeals in the Fifth Circuit in the opinion, appearing on page 37 of the Petition, gave the following as some of the rules in deciding the case, and for brevity instead of citing here the cases substantiating each of these rules we respectfully call the Court's attention to the citations by the Court as shown on page 37 of the Petition, wherein it appears that these rules were laid down by this Honorable Court:

"In the construction of statutes courts will look to the entire act and to its objects and policy. Results which are incongruous or absurd are to be avoided. Where a particular construction of

a statute will occasion great inconvenience or produce inequality and injustice, that view is to be avoided if another and more reasonable interpretation is present in the statute. In the construction of a legislative measure, statutes in pari materia, amendatory acts, and their legislative history may be examined."

CONCLUSION

We respectfully submit that the burden of proof is upon the Petitioner and that writs of certiorari are only granted under special circumstances and should be sparingly exercised and only in cases of peculiar gravity and general importance and we respectfully submit there has been no such showing as to warrant the highest court in the land in reviewing the decision of the Fifth Circuit. The decision of the Fifth Circuit is limited in its nature and the decisions of the Fifth and the Second Circuits can be reconciled, the Fifth Circuit decision being based upon the particular facts before it. Both Courts followed the decision of this Honorable Court in interpreting the word "harmless." The other matters in the decision are incidental and methods of insuring that it is harmless as used. Under the facts before the Fifth Circuit a construction other than the one which has been placed would not have been in accordance with the previous decision of this Court.

We submit that there has been no such showing as to warrant the issuance of the writ of certiorari and respectfully urge the denial of this Petition.

Respectfully submitted,

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NO. 27

IN THE

Supreme Court of the United States

OCTOBER TERM, 1958

MARION B. FOLSOM, SECRETARY OF HEALTH, EDUCATION AND WELFARE,

Petitioner,

v.

FLORIDA CITRUS EXCHANGE, FRANK R. SCHELL, ET AL.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

BRIEF FOR RESPONDENTS OTHER THAN FRANK R. SCHELL

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IN THE

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OCTOBER TERM, 1958

MARION B. FOLSOM, SECRETARY OF HEALTH, EDUCATION AND WELFARE,

Petitioner

vs.

FLORIDA CITRUS EXCHANGE, ET AL.
FRANK R. SCHELL

BRIEF OF RESPONDENTS OTHER THAN FRANK R. SCHELL

QUESTIONS PRESENTED

The questions as stated by Petitioner fail to take into consideration the fact that in the opinion of the Court wide discretion was still allowed in the Secretary to determine the tolerances and to determine if the other requisites existed and to make further investigation and conduct hearings. (R. 183, 2nd paragraph; R. 187, last paragraph)

We submit our view that the questions to be decided on the review could be simply stated as follows:

1. Did the Court of Appeals for the Fifth Circuit commit error in holding that the word "harmless" must be construed in a relative sense and not in an absolute sense and in holding that the Secretary erred in taking FD&C Red No. 32 off of the certified list for use in coloring oranges not for processing and meeting the proper maturity standards when in the manner and quantity as used in the coloring of oranges same was harmless and where there is no showing of likelihood of injury to human beings at the ordinary,

normal levels of use, and when this color had been on the certified list for nearly twenty years and when nothing was learned in the new hearings that was not known at the time of the original certification.

2. Did the Court of Appeals for the Fifth Circuit err when it held that the Secretary has power to certify for a limited use and/or to provide a tolerance and that he erred in entering the order when he construed the Federal Food, Drug and Cosmetic Act as not giving him such powers?

The Court in its opinion (R. 178) states the question as follows:

> "The decision we are to make is whether the Secretary of Health, Education and Welfare is required or permitted to determine if there is a minimum quantity of the coal-tar color designated as FD&C Red No. 32 which can be used in adding color to the skins of mature oranges without danger of impairing the health of those who consume such oranges; and if so required or permitted, and if it be determined that there is such minimum, should the Secretary list and certify such color for such use."

STATUTE INVOLVED

In addition to the portion of the statute set forth in the Petitioner's Brief, we set forth herein Section 402(c) as it appears in the Federal Food, Drug and Cosmetic Act at the Time of the Secretary's order:

> "Sec. 402(c) If it bears or contains a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by Section 346 of this title: PROVIDED, That this paragraph shall not apply to citrus fruit bearing or containing a coal-tar color if application for listing of such color has been

made under this chapter and such application has not been acted upon by the Secretary if such color was commonly used prior to the enactment of this chapter for the purpose of coloring citrus fruit;"

This was subsequently amended by Public Law 672, 84th Congress, 2nd Session, taking effect July 9, 1956 as shown (c) page 3 of Petitioner's Brief.

A portion of Paragraph 371 of 21 U.S.C.A. is pertinent:
(e) ... The Secretary shall base his order only on substantial evidence of record at the hearing and shall set forth as part of the order detailed findings of fact on which the order is based ...."

As is also Section 7 of the Administrative Procedure Act:
"In hearings which Section 1003 or 1004 requires to be conducted pursuant to this section ...
"...

"(c) Except as statutes otherwise provide the proponent of a rule or order shall have the burden of proof ..." 5 U.S.C. 1006.

STATEMENT

The Secretary of Health, Education and Welfare had hearings and issued an order under date of November 10, 1955 removing coal-tar color FD&C Orange No. 1, Orange No. 2 and Red No. 32 from the approved list of harmless colors for the unrestricted use in food, drugs and cosmetics (R. 158). The Certified Color Industry Committee took an appeal to the Second Circuit as to the entire order and the Second Circuit refused to reverse the Secretary. Its opinion appears in 263 Fed. 2d 966.

The Florida Citrus Exchange and a number of growers and packers in the State of Florida and in the State of

Texas took an appeal to the Court of Appeals of the Fifth Circuit in so far as the order affected the use of FD&C Red No. 32 as used in the coloring of mature oranges meeting certain other specifications. Frank Schell also took the review proceedings to the Fifth Circuit. The Fifth Circuit rendered the decision which Petitioner is seeking to review by certiorari. These two cases were briefed separately but argued together and one opinion rendered. (R. 168-191; 246 Fed. 850) Petition for rehearing en banc was filed by the Secretary and denied.

A. The Secretary's Order:

Red 32 was placed on the approved list in 1939 after a public hearing at which its harmlessness was established. The color which was certified as Red 32 had been used for the coloring of oranges prior to the passage of the Federal Food, Drug and Cosmetic Act in 1938. While the Department of Health, Education and Welfare did initiate new studies yet the tests and studies were not to determine whether the color was harmful at the levels as actually used under normal conditions of use and the tests were not made at levels of ordinary conditions of use and the amounts of the color fed to test animals were far in excess of that used in the coloring of oranges, (R. 209-210-211) and the Secretary found the evidence inadequate to support the findings as to the amount of color likely to be ingested by man from his foods, drugs and cosmetics (R. 164, Finding 10). The amount of dye in parts per million in the coloring of oranges is shown as Exhibit 8 (R. 225 and 259) and an analysis of this testimony appears on pages 112, 113, 114 and 115 of the Record. At the levels fed a man would have to eat from 2250 oranges to 45000 oranges per day (R. 113) before he would get enough of the color to show ill effects from the color and could drink 5000 gallons of juice per day without any ill effects attributable to the color. Nothing new was

developed in these hearings that was not known at the time the color was certified in 1939.

Reference is made to possible carcinogenicity as causing investigation. The Commissioner of U. S. Foods & Drug Administration now states no evidence to that effect and action has been misinterpreted.

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The orange is one of the very few fruits which has blossoms, small fruit and fully mature fruit on the tree at the same time; in the Fall until the cool days come a fully ripe and mature fruit may be green on the outside, when cool weather comes the late variety of orange may have a rich color on the outside and not be fully mature inside. Later in the Spring when the chlorophyll (green color) rises in the tree it goes into the leaves and new fruit and likewise goes into the mature and ripe fruit "regreening it", causing it to be green on the outside although it is fully mature and by reason of this it is impossible to sell unless it is colored. Only oranges meeting high standards of maturity may be colored. The use of color does not involve any element of deception as the oranges are marked "color added". Section 402 of the Act specifically prohibits the use of any color to conceal damage or inferiority in a food product. FD&C Red No. 32 was the only color used in coloring oranges and was being sold for such purpose only. (R. 227) The coloring of mature oranges has long been recognized by the Industry, the Department of Agriculture and the Congress as a necessary trade practice and an economic necessity, as will be shown with detailed citations in a subsequent section of this brief. The taking of the colors off of the approved list was not because of any harm or claimed harm as used in the coloring of oranges, the Secretary stating:

"While the scientific evidence so far available does not establish what the lowest safe dosage would be to test animals, neither does it establish a likelihood of injury to man from the use of this color on the exterior of oranges at the levels of use involved.

"...

"The evidence so far available does not establish a likelihood of injury to man from the minute amount likely to find its way into the human diet from the consumption of such colored oranges at the level of use involved." (Report of Secretary of Health, Education and Welfare, February 13, 1956—House Hearings on HR 7732, 84th Congress 2d Sess., p. 3)

3. The Petitions to reopen were overruled on the assumption by the Secretary that he had no right to continue the certification of colors if they were harmful if fed at high levels to test animals, even though the colors were not harmful when used in normal use in limited quantities, and that he had no authority to limit for particular use or to limit the quantities used. (R. 164, Finding 11; R. 165, Finding 12). It is out position that it was this erroneous construction of the law by the Secretary which caused the order to be entered.

Reference is made on page 7 of Petitioner's Brief to the statement of the Florida Citrus Commission. However, the Director plainly stated "it is our understanding from the notice of hearing in the Federal Register that the merits of coloring oranges are not involved in the hearing". (R. 224) Certainly he couldn't assume that the Food and Drug Administration would, on the same type of testimony, reach a different decision than it had in 1939.

B. Temporary Legislation:

1. The introduction of H. R. 7732 was after the Secre-

tary's tentative order had been entered, but before the decision of the Fifth Circuit, and before the Fifth Circuit had granted a stay, but it was not passed until after the Secretary's final order. The coloring of oranges was an economic necessity and had long been encouraged by the Department of Agriculture and, not knowing whether the Fifth Circuit would grant a stay, efforts were made through legislation to continue the use, but as will hereinafter be shown in the argument, it was not intended to limit its use in the event the Court found under the Act that certification could be continued. The words "less toxic" on page 10 of the Secretary's Brief are his own conclusion and are not in the bill itself. The hearings show that the report of the Department had not come in until the day the hearings began, and, when informed of the statement of the Department, the proponents of the legislation agreed to the amendment. The bill, as introduced, appears on page 1 of the hearings before the House Committee and uses the words "more acceptable on the basis of standards set up by the Secretary", etc. (Hearings, House Committee on Interstate and Foreign Commerce on H. R. 7732, 84th Congress, 2d Sess., pp. 2-3) This legislation allowed the use of FD&C Red No. 32 for the coloring of oranges meeting certain standards until March 1, 1959, unless prior thereto another coal-tar color suitable for coloring oranges is listed under Section 406. It is made clear that the use could be continued for such purposes if the Court so determined. The Senate Report concludes with the following words:

> "Inasmuch as the judicial proceeding referred to above have not as yet been concluded, the committee wants to make it clear that if it is finally judicially determined that the Secretary of the Department of Health, Education, and Welfare already has the power to certify F.D.&C. Red No. 32 for use on the exterior of oranges, the instant legislation is not intended to limit or modify that power."

S. Rep. 2391, 84th Congress, 2d Sess., p-3

The primary purpose was to grant a stay for at least three years. Of course, if the Court determined that under the construction of the Act it could certify then the Congress made it clear in its report that it did not intend to limit the Court's decision.

Reference is made in the Petitioner's Brief to Florida and Texas orange growers. Under the Special Act and the decision all users of F-D&C Red No. 32, including the users in California and Arizona, get the benefit. The Record shows the interest of certain California and Arizona growers. (R. 116)

LITIGATION:

The sequence of the litigation is given in the Petitioner's Brief. The two cases before the Court were consolidated. Separate briefs were filed but the cases were heard together. The U. S. Court of Appeals for the Fifth Circuit reversed the Secretary's Order and concluded its opinion as follows:

"After a hearing in 1939 Red 32 was found to be harmless and suitable for use in foods, drugs and cosmetics. The situation as presented on this review was briefly and accurately characterized in a letter from the Commissioner of Food and Drugs to Florida Senators and Congressmen written February 8, 1955. In speaking of Red 32 the Commissioner said:

'Recent investigations show that these colors when fed in substantial amounts, show evidence of toxicity. There is, however, no evidence that, in the amounts used, and in the manner of use, in the coloring of citrus fruit, the product so colored is not safe for human consumption.'

"Unless there is evidence that, in the amounts used, and in the manner of use, oranges colored with Red 32 are unsafe for human consumption, the 1939 finding should not be supplanted by a contrary ruling by which such use is prohibited. It may be parenthetically observed that 'unsafe' is the yardstick for determining tolerances under Section 406(a). A determination may be made by the Secretary on his own initiative or upon the petition of any interested person as to whether coloring is required and, if so, as to whether Red 32 is a harmless coal-tar color for use in coloring oranges and to fix the tolerances, if any, as may be proper for such use.

....

"The order promulgated by Marion B. Folsom, Secretary of Health, Education and Welfare, on November 10, 1955, published in the Federal Register on November 16, 1955, (20 F. R. 8492) will be set aside in so far as said order removes the coal-tar color FD&C Red No. 32 from the list of colors which may be certified for use in coloring the skin of oranges meeting minimum maturity standards prescribed in the State of Florida and Texas; provided, that nothing herein or in the judgment of this Court entered pursuant hereto shall restore said coal-tar color to the list of colors which may be certified for unrestricted use in food, drugs and cosmetics but shall operate to authorize the certification of batches of said color conforming to the specifications for the color appearing at 21 C.F.R. 135.3 (1949 ed.) for the purpose of coloring the skin of mature oranges only; provided further, that the Secretary shall be required to certify only sufficient batches of FD&C Red No. 32 as may be necessary to color the skin of mature oranges from time to time; provided further, that the certificates issued for batches of FD&C Red No. 32 may be limited by their certificate for use in coloring mature

oranges only; and provided further, that nothing herein or in the judgment of this Court entered pursuant hereto shall be deemed to restrict the Secretary from making further investigations and conducting hearings for a determination of (fol. 310) whether the use of Red is required in the production of oranges and to determine the tolerances, if any, that are safe and harmless, as harmless is herein construed and defined."

The Court pointed out in its opinion the difference between this case and the one in the Second Circuit, stating that the identical issues were not presented and a different principle is involved. In the Second Circuit case three coal-tar colors were involved and the uses were all-inclusive (R. 176). The Second Circuit case also had shown that the two cases were different and the Fifth Circuit quoted from the Second Circuit to this effect. (R. 176) In the cases in the Fifth Circuit only one color and one commodity were involved. In the Certified Color Industry case the whole field of foods was involved and there was not testimony as to the amount of color used. In our cases there was testimony as to the amount of color used on oranges. The decision held the words "harm", "harmful" and "harmless" are terms of relation (R. 180) and also held that the Secretary could grant tolerances or certify for a limited purpose and pointed out that the Secretary had on previous occasions so construed the Act. (R. 184) We consider the Fifth Circuit opinion well reasoned and that it show a clear conception of the evidence as well as the law and recognized the rule laid down in U. S. vs. Lexington Mill and Elevator Co., 232 U. S. 399, 34 S. Ct. 337, 58 L. Ed. 658.

SUMMARY OF ARGUMENT

I

Red 32 is not poisonous or harmful as used in the coloring of Oranges.

A. The evidence referred to by Petitioner was based on tests having no relation to the amounts in normal uses in food, or the amounts as used in the coloring of oranges.

B. The statute, read as a whole and in the light of its legislative and administrative history, intended that the uses and quantities of the coal-tar colors be taken in consideration in listing and certifying for use.

A. Petitioner takes the position that there must be zero toxicity. By this test nothing could be certified. The articles of everyday food, and water itself, can be harmful if taken in excessive quantities, and other things considered harmful may, when taken in small quantities, be beneficial.

The tests were made at levels far in excess of the normal levels of use generally and far in excess of the use in coloring oranges. The Petitioner's own witness stated (R. 216-217) that the amount of dye had to be considered in determining whether it is harmless. This was ignored in the findings. The Secretary admitted that the amount likely to be ingested by man was minute, that he could not say that its continued use on oranges would pose a hazard to the public health and there is no present evidence of injury to man.

The summary of evidence shows that a man could drink 5000 gallons of juice per day from color added oranges without injury, and that the feeding of rats was at a rate

7550 times as much color as a man would get if he ate six oranges per day, peel and all. Publications by eminent scientists in this field quoted in the argument point out that the use, quantities and circumstances have to be considered in determining whether a substance is harmful.

B.

1. The legislative history and the administrative background, as well as the Act as a whole, show that it was never intended by the Act to prohibit the listing of coal-tar colors when they were harmless in the manner and quantity as used. The word "harmless" was used in regulations under the previous regulations and yet substances, including coal-tar colors, were certified when it was known that at high levels such substances could be harmful. The hearings on the Food, Drug and Cosmetic Act showed that it is extremely difficult to acquire absolute purety, that it was intended to give legislative sanction to administrative practice and continue the system of certification, and to insure the continued availability of colors. At the time of passage of the Act Congress knew that no coal-tar color could be used for all purposes or in all amounts. In 1939 shortly after passage of the Act, Dr. Calvary, an eminent pharmacologist, at that time Chief of the Division of Pharmacology of the Food and Drug Administration, testifying at the certification hearings on FD&C Red No. 32, showed clearly that the Department then considered both the use and quantity of coal-tar colors in determining whether they were harmful. Nothing new was developed in the hearings on which FD&C Red 32 was decertified that was not developed at the original hearings on which it was certified. The United States Supreme Court decision and the quotation therein from the statement of the Chairman of the House Committee handling the legislation at the time of passage of

the earlier Food and Drug Act plainly states: "Everything that contains poison is not poisonous. It depends on the quantity and combination." All evidence shows that the color is not harmful as used on Oranges. It cannot be used to conceal inferiority as a seperate section of the Act prevents this and the State Laws require a higher standard of maturity before an orange is allowed to be colored.

2. The Food and Drug Administration took the position that it could not certify for a limited use or to prescribed tolerances for coal-tar colors, yet it is shown that it had certified coal-tar colors for limited uses previously and had also certified colors that were harmful if fed at high levels. The Congressional hearings showed time and time again that the Chairman of the Senate Committee and the sponsoring witness appearing for the Food and Drug Administration recognized that the Act contemplated that the Secretary had the right to provide tolerances and to certify for limited purposes. In Section 406 the Secretary is directed to list colors which are harmless for use in food. In Section 504 he is directed to provide for the listing of colors that are harmless for use in drugs and in Section 604 he is directed to provide for the listing of colors which are harmless for use in cosmetics and could be certified for a limited use.

II

There is a clear showing that there is necessity for the use of this color in the production of oranges.

A number of reports of the Department of Agriculture quoted in this brief show that early oranges may become fully mature while still green on the outside while late oranges may be a full rich color and not be mature, and

that after maturity may regreen when the chlorophyll comes into the tree and enters the oranges again in the Spring.

This is the only color now certified for use on oranges and it is not used for any other purpose. It cannot be used to conceal defects or to defraud because State laws require a fuller maturity before coloring is allowed, and specifically prohibits the use of color for deceiving or defrauding.

The Secretary takes the position that added poisonous and deleterious substances were banned without regard to whether the added substances might or might not render the treated food injurious. This is contrary to the entire concept of the Food, Drug and Cosmetic Act. The two purposes of this Act were to protect the public health and to prevent deceit. Neither of these purposes is served by denying the use of a color harmless as used and in such manner that it would be impossible for a human being to ingest enough color from eating oranges to reach any level at which he would be harmed. The Department of Agriculture and the Congress of the United States have approved the use of the coloring and have declared it an economic necessity in the coloring of oranges. The Secretary takes the position that this decision will have far reaching consequences beyond the question of Red 32 for oranges. This statement of the Secretary was made prior to the passage of Public Law 85-929 and this decision will have no effect upon the other food additives. Congress has now spoken again. If this be a reversal of the national food policy which has been followed for years, Congress has itself entered into such reversal, but the policy on oranges is the policy that has been followed for years. Red 32 has been in use for more than 20 years.

III

The Court below did not make its own findings that coloring of oranges is required for production and casting on the secretary the burden to show that safe tolerances can be established. The Court followed the clearly established facts and the law in existence at the time.

The Court of Appeals did not presume the safety of Red 32. It took the Secretary and Food and Drug Administration's own interpretation. The record before the Court showed that it was harmless as used. There was no showing that would justify its being taken from the certified list after 20 years of use. The evidence on which it was taken from the list was substantially the same evidence as that on which it was certified.

In this case the Secretary was the proponent. The Secretary was seeking to take from the certified list a color that had been used for the coloring of oranges for more than 20 years, that had been certified by the Secretary, that had been in use at the time of the passage of the Food and Drug Act. The Administrative Procedure Act, which is applicable to the Secretary, hereinbefore quoted, provides that the proponent of a rule of order shall have the burden of proof. The Food, Drug and Cosmetic Act provided he should base his order only on substantial evidence of record at the hearing. There was a lack of substantial evidence.

IV

Recently enacted legislation

In the closing days of the second session of the 85th Congress the food additive bill, H. R. 13254, which became Public Law 85-929, (72 Stat 1784) was passed. This puts

at rest many of the questions raised by the Secretary, which is applicable to various phases of the argument. This specifically authorizes tolerances and provides a method of establishing safety and the formula therein takes into consideration the proposed use and probable consumption.

This Act, covering the broad field of food additives, puts at rest the fear of the Secretary as to the effect of this decision on sweeteners, oleomargarine and other foods; it puts at rest the fear that this decision will change the food policy because this policy is now established by Congress with the duty of the Secretary to establish tolerances. The reports accompanying this legislation provided that the concept of safety is where the substances are hazardous to health and also takes into consideration the probable consumption of the additive. Certainly, it is not reasonable to assume that that which is applied to the outside of the orange, where any amount likely to be ingested is minute, must be zero toxicity and should be construed by the Secretary as not harmless, when at the same time a greater quantity of material known to be toxic is allowed by tolerance or determination of safety to be placed in food intended for use.

ARGUMENT

I

RED 32 IS NOT POISONOUS OR HARMFUL AS USED IN THE COLORING OF ORANGES

A. The evidence referred to by Petitioner was based on tests having no relation to the amounts in normal uses in food, or the amounts as used in the coloring of oranges.

Petitioner's statements in brief are based on the erroneous construction of the words "harmless" and "suitable

for use," the Secretary taking the position there must be zero toxicity. Therefore the tests were made at levels far greater than normal use.

The statutory language, "harmless and suitable for use" must be construed in the light of the intention of the Act and the testimony and orders in existence as shown by the legislative history. It should not be given an absurd and unreasonable construction. No substance can be said to be "harmless and suitable for use" in the abstract. Strychnine and arsenic, for example, which are highly toxic in relatively low concentrations, are completely harmless and indeed beneficial in the treatment of human diseases when used in the proper quantities under appropriate conditions. On the other hand vinegar and table salt, which are normally not thought of as toxic, can produce illness and death if consumed in excessive quantities. Indeed, the Petitioner's own expert witness, upon whose testimony the orders were based, testified in the hearings in the present proceedings:

"Were you using the term 'harmless' then in the absolute sense that each of the colors were capable of producing harm? A. That is correct.

"Q. In that sense, then, is not common salt capable of producing harm? A. Well, I believe in the case of common salt you have to take into consideration the fact that it is essential to live, so that since you can't get along without some salt, I don't think you could ordinarily consider salt harmful. (R. 212).

"Question. Nevertheless, if you took salt in a quantity of two or three ounces, you may get some bad results from salt? A. There would be some adverse effects from two or three ounces of salt, yes. (R. 212-213)

"...

"Q. Dr. Vos, aren't the amount and method of proposed use of a material necessary data for deciding whether the material is harmless for the use intended? "The Witness: I would say, yes." (R. 216)

"The Witness: Yes, The amount of the dye, of the color, has to be considered in determining whether or not it is harmless." (R. 216)

Again, Dr. Vos, Petitioner's expert witness, testified:

"Well then, these levels were not specifically related to the levels of these colors as actually used under normal conditions of use. No, that was not a part of this.

"Q. Have you any evidence at such levels where the capacity for producing harmful effects was tested at levels of ordinary conditions of use? A. I have very little information on the matter of what the customary levels of use are." (R. 211)

"Q. Dr. Vos, then, you have no evidence as to the capability of producing harmful effects of any of these colors at the level of ordinary use under normal conditions of use, I should say?

Dr. Vos: Without having more thorough information on the actual level of ordinary use, I would hesitate to answer that question.

"Q. Well, you have no evidence at levels other than the levels appearing in the exhibits?

A. That appear in the exhibit, that is correct." (R. 211) "Yes, the amount of dye, of the color has to be considered in determining whether or not it is harmless." (R. 216)

"The Witness: I think it is appropriate the method of use should be taken into consideration. The dyes in question are at present being certified for use in foods, drugs, and cosmetics, and the data which we presented in these exhibits have shown that they are not harmless for use in all of those products. As I have pointed out, we have no data as to whether they are or are not harmless for external application." (R. 217)

From a technical viewpoint a distinguished food chemist sums matters up with the following statement:

"There is no foundation in toxicology for regarding all substances as either poisonous or deleterious, on the one hand, or safe or harmless, on the other. The optical physicist has his absolute white and absolute black, but there are no absolutes for the toxicologist. 'Toxicity' depends on species, age, weight, sex, dosage, route of administration, physiological or pathological state, and manifold other factors comprising 'experimental conditions'. Translation of toxicity data into terms of real or potential effect under any given set of circumstances, as for example, the determination of hazard to any particular segment of the population or to the public health generally, involves considerations that go far beyond toxicity effects in laboratory animals." [1]

Since the Secretary's decision was made there has been Completed a study by the Department of National Health and Welfare, Canada, which confirms a level of no effect in FD&C Red No. 32. A pertinent portion of the report reads as follows:

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1. Oser, CAN A POISON EXIST IN A VACUUM? A Discussion of Section 406(a), 8 Food, Drug, Cosmetic Law Journal, 693, 696 (1953).

"F.D. & C. Orange No. 2, F.D.&C. Red No. 32, and F.D. & C. Green No. 2 in concentrations of 0.03% in the diet did not affect growth, food consumption, or food efficiency in either male or female rats."

CHRONIC TOXICITY STUDIES ON FOOD COLORS By M. G. Allmark, H. C. Grice, and W. A. Mannell. Food & Drug Laboratories, Dept. of National Health and Welfare, Canada, Journal of Pharmacy & Pharmacology Vol. 8; pages 417-425, June 1956

This is far in excess of the four parts per million used on the peel in coloring oranges. Certainly when a dye is used below a no-effect level it is harmless both in fact and in law.

The best scientific opinion agrees with this position; the Ad Hoc Advisory Committee of the National Academy of Sciences in its report of June '56 pointed out that the certification of a compound as "harmless and suitable for use" in food, etc, is unrealistic unless the level of use is specified, and that under the rigid interpretation of this directive many components of ordinary diet could not be certified.

The Report of the Ad Hoc Advisory Committee of the National Academy of Sciences — National Research Council, Reviewing the Food and Drug Administration Research Program on Coal-tar dyes, June 1956, page 17.

Petitioner's brief (page 20) refers to the candy episode. This was not Red 32 but was FD&C Orange No. 1, a water soluble color not used in the coloring of oranges (R. 199-200) and the level of dye in the candy was seven hundredths of a percent (R. 211) and this is 175 times the highest concentration on the peel of the orange. The popcorn episode

was not in the evidence or hearings, happening after the hearings, (R. 155) and there was no evidence as to whether the illness was caused by rancid oil or other ingredients on the popcorn and it contained between 3000 and 9800 parts per million of color, between 750 and 2450 times as much as used on the outside of oranges. We feel that the Secretary erred in even considering occurrences outside the record in ruling upon petition to reopen and the offer of new evidence by Mr. Schnell.

FD&C Red 32 is harmless as used in the coloring of oranges. The record and analysis, as made by the Food and Drug Administration and evidenced by the following quotations, would seem to show there can be no dispute about this:

"There is, however, no evidence that in the amounts used and in the manner of use, in the coloring of citrus fruit, the product so colored is not safe for human consumption."

Statement of Honorable George P. Larrick, Commissioner of Food and Drugs, Department of Health, Education and Welfare. (R. 19)

Excepts from his statement made on hearings on H. R. 7732 are as follows:

"The tests of the toxicity of this color which have been made in the laboratories of the Food and Drug Administration were not designed to learn the effect of this color upon human beings when consumed by reason of its use on the skin of oranges and in the minute quantities that may thereby be ingested, but, rather, the tests were made to determine whether the color is harmless for use in foods generally.

".....

"While the scientific evidence so far available does not establish what the lowest safe dosage would be to test animals, neither does it establish a liklihood of injury to man from the use of this color on the exterior of oranges at the levels of use involved. This color has been in use for the coloring of oranges since the early 1930's. We have not found evidence, so far at least, that injury to consumers has resulted from the consumption of oranges so colored.

"Considering all of the information so far available — and bearing in mind particularly the minute amount of this dye likely to enter the human diet as a result of its use on oranges — we cannot say that its continued use on oranges, not intended for processing, would pose a hazard to the public health.

"... when as here there is no present evidence of injury to man from this particular use of the dye."

Hearings before a subcommittee of the Committee on Interstate and Foreign Commerce, House of Representatives, 84th Congress, Pages 17 and 18

The Senate committee in its consideration of H. R. 7732, which became Public Law 672 , 84th Congress, Chapter 530, 2d Session, 70 Stat 512, also construed the testimony of the Food and Drug Administration along the same lines, because, in its report reading in part as follows, it pointed out:

"...although the Administration testified before the committee that the scientific evidence so far available does not establish any likelihood of injury to man from use of this color on the exterior of oranges at the levels of use presently employed."

Sen. Rep. 2391, 84th Congress 2d Session, Pages 1, 2 and 3

A summary table on the concentration of dye on color-added oranges and its products appears in Exhibit 8, page 259 of the Record.

A summary made by the Food and Drug Administration of the amount used in feeding tests appears at page 160 of the Record. A comparative study of this in its relation to amounts used on citrus fruit and the quantity necessary to be used before affecting man is shown at pages 1, 12-13-14-15 of the Record.

The Petitioner in his brief referred to the fact that Dr. Gerwe is a chemist. Dr. Gerwe is considerably more than a chemist and his experience and education are shown in the Record at pages 19, 20 and 21. Regardless of this, this analysis is not just a study, it is more or less a recap of the actual data in Exhibit 8, R. 259, and R. 160. This shows that a person could drink a 5000-gallon tank full of orange juice every day without suffering any ill effects attributable to the presence of dye stuff. On the basis of a man's drinking 8 ounces of juice per day containing 0.0175 mg of color, this is only 1/80,000th of the intake which caused no affect when the dogs were fed for 5 years (R. 115) The rats were fed at a rate of 7550 times as much color as a man could get, if he ate 6 oranges, peel inclusive, per day. (R. 113) Thus it will be seen that the color was fed at an excessively high level having no relation to its use and there is no showing of any nature that it is likely to cause injury to man at normal levels of use or at the levels of use used in the coloring of oranges. In view of the fact that the color is on the outside, does not penetrate the rag and is not water-soluble, the amount likely to be taken into the human body is only on occasional instances and far less than the amount on the peeling itself.

B. The Statute, read as a whole and in the light of its

legislative and administrative history, intended that the uses and quantities of the coal-tar colors be taken in consideration in listing and certifying for use.

We disagree with the interpretation placed on the Statute by Petitioner. The construction of the word "harmless" has to be considered in a relative sense and not in an absolute sense. If we were to apply the per se doctrine of harmfulness and observe the Secretary's construction then vinegar, salt, pepper and many other articles of everyday diet could not even comply with the definition. The Lexington Mill and Elevator case (232 U. S. 399, 58 L. Ed. 658) shows that poisons in some greater amount are frequently present in potable water, bacon, ham, fruits and certain vegetables. The testimony on hearings on the Food, Drug and Cosmetic bill (Senate Hearings, S. 5, March 1935, p. 261) shows codliver oil contains arsenic, 1.4 to 5.1 parts per million, and shrimp and prawn, 30 parts per million (This is 7½ times the amount contained on the peel of colored oranges), and that fish, dandelions and lima beans contain arsenic.

Inasmuch as the discussion in subheadings B - 1 and B - 3 in Appellant's Brief, beginning on page 21 and page 27 of the brief, will overlap considerably and require the same authorities, we will discuss these together.

1. The terms of 402 (c) and 406 (b) do not require certified coal-tar colors to be wholly harmless for use in all foods, and (3) the legislative history and background of the statute did not intend to prohibit the listing or certification of coal-tar colors for any purpose or use when the only showing of toxicity was when fed at levels far greater than the normal levels of use and far greater than the particular use to which it was to be put.

Prior to the passage in 1906 of the Federal Food and Drug Act a series of appropriation act provisions beginning in 1900 authorized the Secretary of Agriculture to investigate the relationship of preservatives and coloring matters to health, and certain investigations of coal-tar colors were carried out under these amendments.

> Administrative Procedure and Practice in the Department of Agriculture under the Federal Food, Drug and Cosmetic Act of 1938, prepared under the direction of Mastin G. White, Solicitor (1940), p. 65.

The 1906 Act provided in Section 7:
"That for the purposes of this Act an article shall be deemed to be adulterated:...

"In the case of food:...

"Fifth: If it contains any added poisonous or other deleterious ingredient which may render such article injurious to health."

Shortly thereafter the commission was appointed draw up regulations. Although the word "harmless" was not used in the statute the regulations adopted by the Commission consistently used that word. For example, Regulation 12 provided:

"Only harmless colors may be used in food products." and the physiological experimentations leading up to the 1938 legislation treated harmlessness in relationship to the quantities and conditions of actual use rather than in an absolute sense.

The methodology is described as follows:

"The harmless nature of the color is appraised by a study of the results of (physiological) investigations. To be taken into consideration are the minimum lethal dose, as determined by the experiments, the chronic toxicity as demonstrated by damage to internal organs and growth rate, and the various dermal tests."

Herrick, Food Regulation and Compliance, v. 2, p. 998 (1947)

At the time of the passage of the Act Honorable Walter G. Campbell, the then Chief of the Food and Drug Administration of the United States Department of Agriculture, testified to the House Committee on Interstate and Foreign Commerce and his statement definitely shows that there was no claim of absolute purity and that the elements of quantity, use, etc. were to be considered, making reference to the then existing law and to the proposed measures:

"There are very few things, as an illustration, in which you will not find contaminating products in some small degree. With our industrial development, it is extremely difficult to acquire absolute purity, in the production of our food supply...

"Now, under the terms of the present law and under the terms of this measure as I have read it so far, action would be authorized in such cases only when the amount of that added deleterious ingredient was sufficient to injure health. There is a complete exclusion of added deleterious ingredients by this section, except where necessary in the production of the product or where unavoidable. In those instances the poison will be permitted or tolerated in amounts corresponding to the need of using the poison, or its unavoidability, in each particular food. The total of the amount so allocated will not be enough to jeopardize health."

Food and Drug Act — S. 5, Hearings, Committee on Interstate and Foreign Commerce, House of Representatives, 74th Congress, 1st Session, pp. 59-60, Dunn - Food, Drug and Cosmetics Act., Page 1251

Prior to the passage of the 1938 Act, coal-tar colors were not mentioned or treated specifically in the food and drug legislation, but they were certified under regulations of the Food and Drug Administration, and the legislative history shows that it was undoubtedly the Congressional intention to continue in effect a system of certification which had been followed almost from the beginning of the enforcement of the old Food and Drug law in order to make available to the food industry adequate supplies of colors of established safety and purity and that the Act was intended to codify the practices.

At that time there was in effect Regulation No. 13, entitled COLORS AND PRESERVATIVES, which read as follows:

"(a) Only harmless colors and harmless preservatives may be used in articles of food.

Regulations for Enforcement of Federal Food and Drug Act. (S.R.A.D.S. No. 1 issued Nov. 1930)

The intention is clearly shown by the testimony and the reports on the then pending bill. The following is testimony on one version of the Senate Bill:

"Mr. Campbell (at that time Chief, Food and Drug Administration) ...

"In Section 10 ... you will find, in the second paragraph of that secion...that the Secretary is authorized to make regulations, after notice and hearing, for the

certification of coal-tar colors which he finds to be harmless for use in food.

"The Chairman: That is not in the law now?

"Mr. Campbell: That is not in the law now.

"The Chairman: It is there by regulation.

"Mr. Campbell: By regulation we have actually done that. After the existing law became effective the then Bureau of Chemistry, in recognition of the impurities to be found in a great many coal-tar colors and the poisonous character of some of the colors themselves, issued regulations designed to assure the manufacturers and other purchasers that the colors used by them would be non-toxic and free from deleterious ingredients. These regulations established the practice of examining and certifying the purity and safety of coal-tar colors as a method for the protection of the public.

"It is desirable that it be continued. In this language we are asking for legislative confirmation of a practice which has existed since 1907.

Hearings before a Subcommittee of the Committee on Commerce, United States Senate, 73 Cong. 2d Sess. on S. 1944, Dec. 7, 1933 (U. S. Government Printing Office, 1943) pp. 28-29 Dunn 1065-66

Quotations from pertinent reports show the intent of Congress; the Senate report on the 1935 version of the bill

"As a matter of administrative practice in the Department of Agriculture, provision was made for the certification of coal-tar colors shortly after the enactment of the present law...This has resulted in an adequate

supply of harmless colors for all food uses and has operated to the satisfaction of the industry...Under Section 304(b) legislative sanction is given to the administrative practice of the Department in certifying colors."

Sen. Rep. No. 361, 74th Cong., 1st Sess (1935) Dunn, 243.

Similarly, the final report prior to the Conference Report states with respect to the sections:

"Subsection (b) of this section specifically authorizes the listing of harmless coal-tar colors for use in food and the certification of batches of the listed colors which are found to be sufficiently free from impurities to be safe. This continues in effect a system of certification which has been followed almost from the beginning of the enforcement of the old food and drug law in order to make available to the food manufacturing industries adequate supplies of colors of established safety and purity."

House Rep. No. 2139 (75th Cong., 3d Sess.) 1938 Dunn - 820

There is no indication in the legislative history that the language "harmless and suitable for use" was intended to mean harmless in an absolute sense. On the contrary, such an intention would have involved a repudiation of the standards developed and methods used in the administration of the prior Food and Drug legislation by the Department.

Finally, in the light of legislative history it is shown that a major purpose of the coal-tar color provision of the Act was to insure the continued availability of adequate supplies of colors for use by the Food Manufacturers' industry. The

hearings as heretofore cited clearly show that the Congress knew and the Department knew during the hearings and prior thereto that coal-tar colors were not harmless for all uses nor in all amounts. Therefore, legislation, one of the aims of which was to insure adequate supplies of such colors, could not be reasonably construed as meaning the word "harmless" in an absolute rather than a relative manner.

Not only the legislative history but the long time administrative construction shows that it was intended that the word "harmless" was to be construed in a relative rather than in an absolute manner. At the time of the certification of the coal-tar colors in 1939 shortly after the passage of the Act Dr. Calvary, then Chief of the Division of Pharmacology of the Food and Drug Administration, in testifying on certification hearings, (page 233 of the hearings) said:

"Q. Are there in your opinion any coal tar colors that are harmless and suitable for use in all kinds and classes of Foods, Drugs and Cosmetics.

"A. (Dr. Calvary), No, in my opinion there are no coal tar colors that are harmless and suitable for use in all kinds and classes of Foods, Drugs and Cosmetics..."

Later in the hearings he made the further statement: (page 243 of the hearings)

"Q. What do you mean by the terms that you have used, 'harmless and suitable for use'? The use to which the color is to be subjected?

"A. Yes, by harmless and suitable for use for the purposes indicated, we mean that in the concentrations that these substances are used for coloring

purposes, it is our opinion that no harm can come from them to the user when used in the concentrations for which they are designed"...

"Q. In considering the amount used, does the tinctorial property of these coal tar colors have some bearing on the amount used?

"A. Yes, the tinctorial properties of the coal tar colors is such that when they are used in foods, drugs and cosmetics they are used in relatively small percentages, and one takes that into consideration when one speaks of the toxicity of these substances assumed as harmless and suitable for use in drugs and cosmetics."...

"Q. Dr. Calvary, how do you arrive at percentage of color which should be allowed as harmless and suitable for use in foods, drugs and cosmetics?"

"A. We arrived at the conclusion that we have concerning the use of these from our conferences with the cosmetics, food and drugs manufacturers, and after learning from them what the percentages are which in most cases are a fraction of a per cent, we based our reasoning on that premise. The colors are not certified for use as colors to be consumed as colors. They are certified — at least we are permitting the listing of these for certification — on the basis of the fact that they will be used as we have been told they are being used at the present time, that is, in small percentages."...

Hearings U. S. D. A. FD & C. Docket No. 4 Feb. 7, 1939, pp. 233 and 243; Hearings USDA Docket FD&C 9, July 1939, Page 63

We respectfully call attention to the fact that the testi-

mony of Dr. Vos, hereinbefore quoted, upon which FD&C Red No. 32 was decertified, develops nothing new that was not developed in the testimony of Dr. Calvary just quoted and upon which the color was certified, and it will be seen that when the purpose of the Act was fresh in the minds of those who were to administer it it was recognized that concentrations and the purposes had to be considered in determining what was harmless.

The court decisions recognize that the terms must be relative and not absolute and that many food substances contain toxic materials.

In the case of Lexington Mill and Elevator Co. vs U. S., which was a case on adulteration of flour, the Court of Appeals reversed the District Court holding that the construction of the Trial Judge was strained and among other things said:

> "The trial Judge decided that if the added substance was qualitatively poisonous, although in fact added in such minute quantity as to be non-injurious to health, it still fell under the ban of the statute...There is no warrant in the statute for such strained construction. The object of the law was evidently:
>
> (1) To assure to the purchaser that the article was what it purported to be and
>
> (2) To safeguard the public health by prohibiting the inclusion of any foreign ingredients deleterious to health.
>
> (Citing Hall-Baker Grain Company vs. U. S., 198 Fed. 614)
>
> Lexington Mill and Elevator Co. vs. United States, 202 Fed. 615

Page 621 of the opinion is very enlightening and it shows the fact that poisons in some greater amounts are frequently present in potable water, bacon, ham, fruits and certain vegetables, etc.

This case went to the Supreme Court of the United States and in the opinion the Supreme Court upheld the decision of the Circuit Court of Appeals, and among other things, said:

"It is evident from the charge given and request refused that the trial Court regarded the addition to the flour of any poisonous ingredient as an offense within this statute, no matter how small the quantity and whether the flour might or might not injure the health of the consumer. At least such is the purpose of the part of the charge above given and if not correct it was clearly misleading, notwithstanding other parts of the charge seemed to recognize that in order to prove adulteration it is necessary to show that the flour would be injurious to health... (Page 661)

".....

"If it cannot by any possibility when the facts are reasonably considered, injure the health of any consumer, such flour, though having a small addition of poisonous or deleterious ingredients, may not be condemned under the act. This is the plain meaning of the words, and in our view needs no additional support by reference to reports and debates, although it may be said in passing that the meaning which we have given to the statute was well expressed by Mr. Heyburn, chairman of the committee having it in charge upon the floor of the Senate (Congressional Record, vol. 40, pt. 2, p. 1131):

" 'As to the term "poisonous", let me state that everything that contains poison is not poisonous. It depends

upon the quantity and the combination. A very large majority of the things consumed by the human family contain, under analysis, some kind of poison, but it depends upon the combination, the chemical relation which it bears to the body in which it exists as to whether or not it is dangerous to take into the human system' " (pp. 662 and 663)

Lexington Mill and Elevator Co., 232 U. S. 339, 58 Law Ed. 658

In the following case it was definitely established there was arsenic in the color, but notwithstanding this, the Court said:

"(2) We are not satisfied, however, that arsenic in such quantity as to be injurious to health was present. ...The government certifies color when arsenic is present, and when only slightly less than that found in the confiscated product.

"The evidence in the case does not present a disputed issue of fact, but rather a difference between chemists over the meaning of the words 'deleterious ingredient, injurious to health.' ...In other words, one would be required to drink 150,000 bottles of soda before he would have consumed a quantity of arsenic sufficient to equal the 'dose'.

"...The Congress has not assumed to define with absolute particularity what is or what is not injurious, and we cannot accept the testimony of the one witness who testified for the government to the effect that the word 'injurious' is an absolute term. Rather do we conclude upon the testimony before us that the arsenic present in the quantity disclosed was not injurious."

W. B. Wood Manufacturing Company vs. United

States, 286 Federal Reporter 84 Page 86 of the Opinion.

Just as the government wanted the word "poisonous" and the word "injurious" in the Lexington case to be construed in an absolute rather than a relative sense and in the Wood case wanted to have the word "injurious" so construed, so in this case does the Petitioner seek to have the words "harmless" and "harmful" construed in an absolute sense. The Court of Appeals of the Fifth Circuit followed the example of the U. S. Supreme Court in the Lexington Elevator case, supra, and did not agree with the Secretary as to his construction of the word "harmless". Neither did the Second Circuit agree with his construction of the word "harmless." The Lexington Elevator case was good law then and is still good law today. The use of the word "harmful" or the word "harmless" did not change the criteria. The word "injure" means to harm (Websters New Twentieth Century Dictionary, 2d E. page 944); to do harm to (Ballantine Law Dictionary, page 650.

The Court held that the small amount of arsenic in soda water was not injurious, that is without injury, so the minute amount of color on the rind of oranges would be harmless, that is without harm.

In the discussion of the point Petitioner, page 33 of the brief, refers to what was Section 3(e) of S. 2800. It will be observed, however, that this was primarily to do away with the labelling requirement. The citrus industry was already using the color they now use an it was considered has harmless and the Department, as pointed out by the Court of Appeals of the Seventh Circuit in the Wood case just cited, had been certifying a color as harmless when arsenic was present and considered this harmless because the regulations in effect promulgated by the Department, hereinbefore

set forth in this brief, used the word "harmless." The failure to include Section 3(e) in subsequent drafts of the bill did not mean a new interpretation of harmless, but merely meant abandonment of the proposed amendment regarding certain labeling requirements. The hearings clearly show this — Explanation of Congressman Wilcox, page 189, H. R. Hearings, Food, Drug & Cosmetic Bill 1935.

Petitioner's brief, page 23, makes the claim that one could use the color to achieve any tinctorial hue he desires and in any amount. This is incorrect. The Federal Food, Drug and Cosmetic Act prohibits the use of color to conceal inferiority and the Florida State statute prohibits dyes or colors that contain certain known poisons "or any other substances known to be injurious to health in excess of the amounts thereof permitted in certified food colors by regulations of the United States Department of Agriculture." (Section 601.75, Florida Citrus Code, F.S.A.) It, likewise, prohibits the colors that are "injurious to citrus fruit or to its keeping qualities or to result in the creation of an unstable and unsatisfactory color on the peel of the citrus fruit." (Sub-paragraph (4), Florida Citrus Code, F. S. A. 601.76) A color in excess of natural varietal colors is not allowed. The Florida implementing legislation passed as the result of conferences and cooperation with the Food and Drug Administration contemplates that the amount of color is to be considered and that certain ingredients are to be tolerated.

If the word "harmless" meant what the Food and Drug Administration claims it means there would be no need for the express distinction between the use of a color, under 406(b) for use in food, under 504 for use in drugs, and under 604 for use in cosmetics. If a color is harmless under the Food and Drug Administration interpretation it should

be suitable for use in any food, drug or cosmetic. There are many colors permitted for use in drugs and cosmetics that may not be used in food. The very fact that the problem of colors is dealt with in three separate sections of the Act is obvious proof that Congress recognized that some colors may be harmless under some circumstances of use but not under others. This is a clear recognition of the fact that safety must be related to conditions of use. Again the Secretary, when he lists a harmless color as an external D & C color, shows that he realizes that its use has to be considered and that it is different from an FD&C color. In our case the Secretary took colors off one list and put them on another, showing that the use must be considered.

2. The tolerance provision of Section 406(a) is applicable to coal-tar colors and the Secretary has power to certify for limited use and/or provide tolerances. (Petitioner's Brief 2)

The Secretary takes the position that he has no right to prescribe tolerances and the limitation of use. We disagree with him and feel that the whole history of the Act shows that he does have such right and the Court of Appeals of the Fifth Circuit so held.

From the statements made by the Secretary and F.D. and C officials the deleting of FD&C Red No. 32 was brought about by this erroneous construction of the law because the statements made in other parts of the brief recognize there is no likelihood of harm by reason of its use as such in the coloring of citrus fruit. In the certifying of Violet No. 1 the Department had previously recognized that they must tolerate because in certifying this color the Secretary said:

"The amount of color fed the animals in the tests referred to in finding No. 12 was far in excess of the

amount that any human might obtain as a result of food colored with F. D. and C. Violet No. 1."

Finding of Fact No. 13, 15 Fed. Reg. 3517 (June 7, 1950)

The Congress recognized that the color could not be harmless in an absolute sense and they recognized that limitations or tolerances would be in order. Otherwise, why should the Congress provide that the Administration shall promulgate regulations providing for the listing of coal-tar colors. It had been testified to at that time that all matter contained some deleterious matter and it was known that no coal-tar color was harmless and suitable for use in all kinds and classes of foods. Therefore, it would have been absurd and unreasonable to feel that Congress would have said "shall" when it knew no coal-tar color was suitable for all foods. Congress gave the Secretary broad power to make regulations.

The testimony of Mr. Campbell, sponsoring legislation and appearing before the committee for the Food and Drug Administration, pointed out at the hearing on the Food and Drug Bill (75th Congress, 1st Session, pages 358 and 359) that it authorized the establishment of tolerances for or the total prohibition of added poisons.

Section 402 with reference to adulteration on account of general ingredients and Section 402(c) with reference to adulteration by reason of containing a coal-tar color other than one from a batch which had been certified, both refer to Section 406, not 406(b) or 406(a), but 406, which shows that the Congress intended all of Section 406 to be construed together and it authorizes the granting of tolerances on coal-tar colors. Tolerances or certifying for specific uses are only methods of insuring that a color is harmless. If it

is without poison or deleterious substances then it can without question be certified. If there is some such substance then the tolerance provisions apply. This was recognized by Dr. Calvary, Chief of the Division of Pharmacology, Food and Drug Administration, as previously quoted, and was well pointed out by the Court of Appeals of the Fifth Circuit:

> "We see no reason for supposing Congress intended to permit the use of toxic substances, including toxic colors other than coal-tar products, in safe and harmless quantities and to prohibit the use of coal-tar colors in safe and harmless quantities." (R. 183)

This is good sense, particularly in view of the fact that coal-tar colors are not just colors that are capable of being made from coal tar chemicals but would include colors made from vegetable matters.

Tolerances are allowed for residual in apples, peaches, cherries and other fruit on which it is known that the outside peeling or rind will be eaten. Certainly we cannot assume that Congress, which specifically recognized the coloring of oranges, should require a higher standard and allow less flexibility for an oil soluble color that does not even penetrate the rag of the fruit as it is only placed on the outside on the rind which is not eaten and only in extreme instances and in infinitesimal amounts might get into the juice, so its undoubted purpose was to construe the word "harmless" in the light of the manner and quantity as used.

In addition to the mandatory provisions of the Act providing "The Secretary *shall* Promulgate regulations providing for the listing of coal-tar colors which are harmless and suitable for use in food." (Emphasis ours) (21 U. S.

C. A. 346a) Powers which could also authorize tolerances appear elsewhere in the Act.

Chapter VII, General Administrative Section, provides additional authority to promulgate regulations for the efficient enforcement of this Chapter, except as otherwise provided in the Section is vested in the Secretary. (21 U.S. C.A 371 (a)).

The Wood case, supra, points out under the old Act that the Secretary had provided tolerances for the inclusion of arsenic and other toxic extraneous materials in such colors. This was under the general powers prior to the passage of the 1938 Act. Although the Secretary now claims he has no authority to certify for a special use, yet in his Order, he took these colors off of one list and relisted them for external use in cosmetics, a restricted use. The Secretary has previously in Section 135.1 of the Regulations provided a restricted use by providing that the regulations for the certification of colors shall not authorize the certification of any such color for use in any article which is applied to the area of the eye. There was no specific statutory authorization for this limitation upon its use but it was upheld by our own Court of Appeals for the Fifth Circuit in Byrd vs. U. S., 154 F. 2d 62, wherein the Court said:

> "The statute contemplates that he shall not arbitrarily exercise his power, but shall act only upon a conscientious judgment derived from a consideration of the facts and conditions to which the regulation is to be applied."

Byrd vs. United States, 154 F. 2d 62 (5th Cir. 1946)

The Secretary had also previously listed a color for use for external application to egg shells. (20 F. R. 9554, 21

C.F.R. Par. 9.3(c)) This was pointed out by the Court of Appeals of the Fifth Circuit, page 184 of its opinion wherein the Court said "We merely observe that the Secretary restricted the use of a group of coal-tar colors to a single food and we feel he was empowered to do so."

3. The legislative history and background show that Congress intended that the purposes and uses should be considered in the listing of and certifying of coal-tar colors and that tolerances could be granted.

The entire record of the legislative hearings shows no intention to distinguish between coal-tar colors and other colors or food additives. Mrs. Baldwin, First Vice-president of the National League of Women Voters, testifying, page 39 of Senate Hearings, referred directly to Section 503 which was the coal-tar section for cosmetics and stated:

"... we do know that you can include in a cosmetic a certain amount of poison."

Senator Copeland, replying, among other things, said:

"Well, of course, that is covered by the general term that it should be deemed to be adulterated if it bears or contains any poisonous or deleterious substance which may render it injurious to health. So the Department itself would have to determine whether there was too much of this or that poison in the cosmetic, if there is any there."

Senate Hearings on S. 5 before Subcommittee of the Committee of Commerce, U.S. Senate, 74th Congress, 1st Sess., page 39.

In the colloquy between Chairman Copeland and Mr. Campbell in the Senate Hearings, among other things, the following was said:

The Chairman: "Here the quantity of harmful substances would be left to regulation by the department?"

Mr. Campbell: "That is right."

...

The Chairman: "I assume that you desire, as pictured in this bill, that the department, through some methods they shall work out, shall establish these various tolerances and then if you have them disputed in court, there would be one determination that a certain amount of arsenic would be the limit that can be used in a foodstuff. And, then, by that one decision, you would then establish that that was the legal limit of the use of arsenic; is that right?"

Other statements of Mr. Campbell bear out the same thing.

"We have tolerances now, merely administrative tolerances."

He also pointed out that the problems were so complex and so shifting "that they do not lend themselves effectively to rigid legislative expression" and that in figuring out who would determine what the physiological effect of the deleterious ingredients would be this "does not mean a cloistered group of individuals who do not know anything about marketing operations of food products, necessarily. . ." (Dunn 1059-60-61)

"We can deal in every individual case, under the language of the present law, with the particular product and prevent its being marketed if it contains any added deleterious ingredients which may be likely to injure health. We can take care of that situation in each individual case; fruit in one instance, eggs in another, and any other article of food." (Dunn 1062)

"We would determine the tolerances under the pro-

visions of this section exactly as we do the tolerances under the provisions of the existing law." (Dunn 1057)

"We propose this legislation with a full and complete understanding of the necessity for the protection of the public health not only but also of the protection of the economic interests of the growers."

". . . We recognize, at the same time, that tolerances must be established for fruit and vegetables, but should be restricted to amounts safe for consumption." (Dunn 1063)

Showing the discretion of the Secretary as to determining what is harmless, he also said:

". . . that the Secretary is authorized to make regulations, after notice and hearing, for the certification of coal-tar colors *which he finds to be harmless* for use in food (emphasis ours) Dunn 1065

On the next page he refers to safety, so there is nothing in the record to show a desire for discrimination against coal-tar colors in allowing tolerances and that the safety factor and not absolute purity was the goal. His statement, Dunn 1147, shows that this is merely asking for confirmation of an administrative practice that had prevailed for years in the certification of coal-tar colors. This administrative practice had been to allow certification even when at high levels it was harmful. At page 1153 his testimony shows "proper variations to expect under proper methods of control, . . ."

In a report to Representative Carl E. Mapes, House of Representatives, March 29, 1938, the then Secretary of Agriculture, H. A. Wallace, set forth in House Minority Report (Dunn 837)

"The bill delegates to the Secretary of Agriculture the

quasi-legislative power to ascertain the necessary technical facts and supply the details that will complete these definitions, thus effectuating the legislative will.

"The Secretary is entrusted with these powers in connection with sections 401, 403 (j), 404 (a), *406(a) and (b)*, 501 (b), 502 (d), 502 (f) exclusive of proviso, 502 (h), 504, and 604. These sections are extremely important. They relate to the identity and quality of food, to requirements with respect to special dietary food, to contaminated food, to poisonous substances in food, to coal-tar colors in food, drugs and cosmetics," etc.

It will be noted here that this report specifically construed the Act as allowing the Secretary to ascertain the necessary technical facts and supply the details and that it referred to both 406(a) and 406(b) and other regulatory sections as applying, among other things, to coal-tar colors in food.

David F. Cavers, Professor of Law, Duke University, who assisted in the drafting of the original Senate Bill, points out the difficulty of spelling out all the regulations in a single statute, Dunn 1180, and states:

"The facts which furnish the basis of the regulations are, of course, to be determined by the Secretary."

Instead of legislation proposing to get away from the Supreme Court interpretation the record shows it was intended to preserve the language of the Supreme Court decision. As Mr. Campbell pointed out in response to a question by Senator Clark, one of the purposes was "...and second, to preserve the use of the language which had already been considered by the Supreme Court." (Dunn 1140)

The Amended Senate Report, No. 152, 75th Congress, 1st Sess. (Dunn 687) points out that the bill must impose no

hardship which is unnecessary or unjustified in the public interest and will enable honest business to be carried on without interference except as is necessary to safeguard public health. There is no showing that the action of the Secretary in delisting this color was necessary in the public interest or to preserve the public health.

In the House, explaining wherein S. 5 differed from the previous law, knowing that coal-tar colors had been certified without specific legislative authority in the present law, Representative Chapman did not even make reference to the certification of coal-tar colors. His explanation of tolerances limiting the amount of added poison to the extent necessary to safeguard public health made no distinction between coal-tar colors and other colors or foods. (Dunn 577)

II

THERE IS A CLEAR SHOWING OF THE NECESSITY FOR USE OF THIS COLOR IN THE PRODUCTION OF ORANGES

We have previously discussed the applicability of Section 406 and 406(a) to coal-tar colors. The Schell brief deals in detail with the history and development of the coal-tar color and its necessity but the record shows that 59 per cent of the fruit has been colored since the certification of this color and in some areas and some packing houses 100 per cent. The Department of Agriculture has long recognized the necessity for the use of such a color and this will be developed more in detail in Sub-section B of this portion of the brief.

A. Section 406 was intended as a method for allowing tolerances and at the same time protect the public health.

'There was no flat prohibition against the use of a harmful substance when not harmful in the manner and quantity as used.

Section 402(a)(1) says:

"If the quantity of such substance in such food does not ordinarily render it injurious to health"

Section 402(a)(2) says:

"If it bears or contains any added poisonous or deleterious substance which is unsafe."

Petitioner argues that each food should be considered alone and we feel that each article can be considered alone. Just as Senator Copeland said "so much of this or that" a tolerance for one fruit or vegetable can be one thing and another amount for another fruit or vegetable, and the Secretary knowing how much color is being certified can limit the amount by knowing the entire possible intake from all sources.

FD&C Red No. 32 was being used prior to the passage of the Act. Shortly after the passage of the Act hearings were held and it was certified as safe for use in foods and has been in use for more than 20 years. At the time of filing of these proceedings more than 250 million boxes of oranges had been colored without complaint or any injury to man. For the seasons 1945-46 through 1956-57 68.2 per cent of all oranges shipped out of the State of Florida used this color. The color-added range from season to season ran from 60 per cent of oranges shipped to 76.3 per cent of oranges shipped. (Annual Report, Citrus Inspection Bureau, Florida Department of Agriculture, 1958) The hearings on H. R. 7732, supra, show a table of shipments for certain periods and show that 100 per cent of oranges in Texas in certain seasons were color added.

The Department of Agriculture and the industry have for years recognized the necessity of coloring oranges in order to market them and certainly the production of a fruit does not end when it is on the trees.

B. FD&C Red No. 32 is the only certified color used in the coloring of oranges. Its use is required in the production of oranges and cannot be avoided by good manufacturing practice.

Petitioner's brief states that the Secretary was not at all concerned with the question whether Red 32 is required in the production of oranges and then seeks to argue that the record does not show that it is required in the production of oranges. We must again call attention to the fact that all necessary elements for the certification had been established in the 1939 hearings. The Secretary in the hearings on which he decertified the three colors was considering only one point, whether at any levels the colors were harmful. The record shows, as has been discussed elsewhere, that it was harmless as used in the coloring of oranges and there is no showing that the color was harmful in any normal levels of use.

Elsewhere in this brief we have pointed out that this is the only color certified that is used in the coloring of oranges and that it is not used for any other purpose. The record and scientific publications clearly show that in order to market oranges in fresh form it is necessary to color. The U. S. Department of Agriculture, which for a long period of time had within it the Food and Drug Administration, in several of its technical and official publications so stated:

"It is well known that citrus fruits grown under certain climatic and cultural conditions may be mature and highly desirable for food while the skin of the fruit is

still green in color . . . In general, when it reaches full color on the trees the fruit in this region is characterized by a low acidity, with a comparatively high sugar content, and the overripe fruit is inclined to be insipid in flavor. It is important then, if this fruit is to be furnished to the consuming public in its most desirable condition for food, that it be harvested before it becomes yellow on the trees . . . It is evident, then that some method of treating this fruit so that it would assume a rich orange yellow color early in the season, when it is most desirable for food, would be of benefit to the industry and to the consuming public alike."

U. S. D. A. Bulletin No. 1159, August 1923

"Some of the early fall varieties of oranges and grapefruit ripen while the fruit is still green in color . . . There is, therefore, no definite relation between flavor or maturity and the color of the fruit while on the tree. However, there is a very significant relation between the color of the fruit offered for sale and the price it will bring, and citrus fruit producers have always faced the problem of making the color of ripe fruit match its flavor."

U. S. D. A. The Year Book for 1932, pp. 134-137

"It is obvious, then, that treating fruit which is physiologically mature or has reached a stage in its development at which it has high dessert quality, so that it assumes a color or appearance pleasing to the eye and has a higher decorative value, is a legitimate practice in marketing and one which should be encouraged."

U. S. D. A. Bulletin 1367, May 1926, 167.

The Senate Report on H. R. 7732, pages 1 and 2 of the Report, recognizes the economic necessity and the lack of

likelihood to cause injury and uses the following wording:

"This practice has become an economic necessity for a major segment of the orange industry, since large quantities of oranges grown in Florida and Texas would meet with strong consumer resistance if they are not artificially colored.

...

"The need for this legislation arises because the only coal-tar color suitable for coloring oranges (F. D. & C. Red 32) has been stricken from the approved list by the Food and Drug Administration. The Administration, after public hearing, concluded that this particular coal-tar color was not harmless but was toxic, and that under the present law the Administration could not list this color as 'harmless and suitable for use in food' although the Administration testified before the committee that the scientific evidence so far available does not establish any likelihood of injury to man from use of this color on the exterior of oranges at the levels of use presently employed."

Sen. Rep. 2391, 84th Congress, 2d Session, Pages 1, 2 and 3

The House Report contained substantially the same matter. The Court of Appeals for the Fifth Circuit also pointed this out in its opinion (R 182) and pointed out that it is as important that a food be marketable as that it be palatable.

The principal purpose of producing any agricultural commodity on a large scale is for marketing We have passed the time when the grower merely raises for his own consumption and the words "production thereof and good manufacturing practice" embrace those things that are necessary to get the product ready to ship.

The petitioner refers to the use of poisonous artificial sweeteners. This is a matter in which the artificial sweeteners are included in the food itself and where other sweeteners can be used in the foods and is a different problem entirely from the coloring of the outside of oranges where only a minute quantity at most can get into the orange itself. In the brief it refers a number of times to a list of colors available for restricted use. We submit that this is one of the errors made in his original ruling in taking the position that he could not certify for a restricted use. The Secretary would limit the term "required in production" to the substance required in growing the fruit, not post-harvest treatment.

Petitioner seeks to limit the meaning of "required in production" and cited in support thereof (Brief, p. 43) the case of Armour & Co. vs. Wantock, 323 U. S. 126, 129-130, but we feel the construction of this case is favorable to our side. The Court said:

> "So too, no hard and fast rule may be transposed from one industry to another to say what is necessary in 'the production of goods.' ". (Headnote 3)

This case involved the question of whether a watchman was under the Wage and Hour Law and whether he was engaged in the production of goods for commerce and the case held he was. The Court also used rather interesting wording:

> "Whatever terminology is used the criteria is necessarily one of degree and must be so defined."

This case cited the case of Santa Cruz Packing Co. vs. N.L.R.B. (303 U. S. 453, 467; 82 L. Ed. 954, 960; 58 S. Ct. 656) and also pointed out that the restrictive words like indis-

pensable would not have the automatic significance sought to be given them by Petitioner.

Under the Fair Labor Standards Act there are a large number of cases dealing with production and the production of goods for commerce and it has been held repeatedly that grading, packing and selling were production of goods for commerce. (Walling vs. McCracken County Peach Association, D. C. Kentucky 50, Fed. Sup. 900-904; Sikes vs. Lochmann, 132 P. 2d 620-624; 156 Kan 223) If the packing house employees are an essential part of production the coloring of oranges is a part of production because packing and processing are a part of production and this is a portion of the processing.

The Court of Appeals of the Fifth Circuit in its opinion (R. 179) pointed out that they were reviewing the order with respect to the coal-tar color Red 32 as used in the coloring of the skins of oranges, that they are not confronted with the broad questions that were before the Second Circuit in the Certified Color Industry case. It reversed the Secretary only in part and pointed out the powers of the Secretary so a construction of the opinion should not give rise to the fears expressed on page 44 of Petitioner's brief.

The Secretary takes the position a substance harmful at any level or any use was banned without regard to whether the added substance might or might not render the treated food injurious. This is contrary to the entire concept of the Food, Drug and Cosmetic Act. The two purposes of the Act were to protect the public health and to prevent deceit. Neither of these purposes is served by denying the use of a color harmless as used and in such manner that it would be impossible for a human being to ingest enough color from eating oranges to reach any level at which he would be harmed. The Department of Agriculture and the Congress

of the United States have approved the use of coloring and have declared it an economic necessity in the coloring of oranges. The Secretary takes the position that this decision will have far reaching consequences beyond the question of Red 32 for oranges. This statement of the Secretary was made prior to the passage of Public Law 85-929 and this decision will now have no effect upon the other food additives. Congress has now spoken again. If this be a reversal of the national food policy which has been followed for years Congress has itself entered into such reversal, but the policy on oranges is the policy that has been followed for years.

III

THE COURT BELOW DID NOT MAKE ITS OWN FINDINGS THAT COLORING OF ORANGES IS REQUIRED FOR PRODUCTION AND CASTING ON THE SECRETARY THE BURDEN TO SHOW THAT SAFE TOLERANCES CAN BE ESTABLISHED. THE COURT FOLLOWED THE CLEARLY ESTABLISHED FACTS AND THE LAW

The point made by the Secretary, pp. 44-45 of his brief and elsewhere, referring to the use of similar substances in other foods, is now made obsolete by reason of the passage of Public Law 85-929, 72 Stat. 1784.

The Court of Appeals did not presume that proper tolerances could be established, it left the matter to the Secretary as is clearly shown by the following quotation from the opinion:

> "... and if he finds that such use is so required, then to determine the quantity, if any, that can be tolerated as safe, and by regulation to limit the quantity to such extent as he finds necessary for the protection of public health...."

(R. 183) and in the concluding sentence of the opinion. (R. 187)

A. Neither did the Court establish a tolerance but determined that the Secretary could provide a tolerance for coal-tar colors. The record shows that only four parts per million of color is used on oranges, far less than the intake of many substances in normal foods; that on the basis of the amounts fed to animals it would be impossible with this small percentage of color for a human being even to intake enough to be harmful because he would never have the capacity to eat that many oranges or drink that much juice. The quantity on the oranges and in the juice appears in the record.

The reason we have quoted the Department and Commissioner Larrick's statements before the committee is that this is their own evaluation of what they had found, showing that the amount to be ingested was minute, that it had not been shown that it would be harmful and that there was little likelihood of its being harmful.

The Petitioner takes the position that the facts needed to establish safe tolerances do not exist; the record does show the amount used on oranges; the Allmark study shows for FD&C Red 32 a point of no-effect far in excess of the amount used in the coloring of oranges and the Commissioner had the results of his own studies, but, as we have pointed out before, the Court did not say this was a tolerance. It merely provided, among other things, that the Secretary could establish a tolerance and he can take more testimony if he desires.

The comment is made by the Secretary on the statement of Dr. Gerwe. Dr. Gerwe is more than just a chemist as will be seen by the report of his experience, supra, and he ana-

lyzed the evidence in its relation to man. The Secretary had felt that if a coal-tar color would harm at any level he could not certify it and must take it off of the certified list, that he had no right to limit the level of use and that he had no right to certify for particular use, therefore the tests were made at abnormally high levels to determine if the colors were harmful at any level. The Court pointed out that "harmless" should be construed in a relative sense, that he could limit the amount and that he could certify for particular purposes, but clearly left the determination of the necessity, the quantity and the use to the Secretary.

Answering the Note No. 21 of the Secretary's Brief, pp. 48-49, this comment does not take into consideration exports and that no coloring process is 100 per cent efficient, that considerably more color is used than goes into the rind of the orange, that considerable of the residue is rinsed off and discarded, that leaves, twigs, etc. get into the coloring bath and that these baths are discarded with substantial amounts of color still in them.

B. The Court of Appeals did not assume the safety of Red 32. It took the Secretary and the Food and Drug Administration's own interpretation of what the evidence showed. The record before the Court showed that it was harmless as used. In this case the Secretary was the proponent, the Secretary was seeking to take from the certified list a color that had been used for the coloring of oranges for more than 20 years, was in use prior to the passage of the Food, Drug and Cosmetic Act, and, after hearings in which Dr. Calvary had testified that no coal-tar color was harmless for all uses, had been certified in 1939 "as harmless and suitable for use in foods".

The Administrative Procedure Act, which is applicable to the Secretary, hereinbefore quoted, provides that the pro-

ponent of a rule of order shall have the burden of proof. The Food, Drug and Cosmetic Act provided he should base his order only on substantial evidence of record at the hearing. There was a lack of substantial evidence warranting the color being taken off the list. The evidence, as quoted in other parts of this brief, was about the some on which the color had been certified.

The Secretary, Brief page 51, quotes the Supreme Court to the effect that the Act does not contemplate that the Court should substitute their own judgment for that of the Administrator. The debates and records clearly show the strong intent for Court review of these orders as a safeguard against erroneous action. The Supreme Court points out that certain interpretations of the statutes are not the substitution of the will of the Judge for that of the legislature.

> "It is a familiar rule that a thing may be within the letter of the statute and yet not within the statute, because not within the spirit nor within the intention of its makers."
>
> "'This is not the substitution of the will of the Judge for that of the Legislator, for frequently words of a general meaning are used in a statute, words broad enough to include an act in question, and yet a consideration of the whole legislation or the circumstances surrounding its enactment, or the absurd results which follow from giving such broad meaning to the words, makes it unreasonable to believe that the Legislator intended to include the particular Act. (Holy Trinity Church vs. United States, 145 U. S. 457, 459, 12 Supreme Court 511, 512, 36 Law Ed. 226)"

The Supreme Court of the United States in concluding the case just above recited used this language:

"It is the duty of the Courts under those circumstances to say that however broad the language of the statute may be, the act, although within the letter, is not within the intention of the legislature, and cannot come within the statute."

In a Food and Drug case the Circuit Court of Appeals in the 2nd Circuit used this wording as to the interpretation of the then Food and Drug Act:

"The general language should not be so construed to ruin a legitimate business and yet remedy none of the evils the statute was designed to remove."

French Silver Dragee Co. v. United States 179 Federal 824

The Court of Appeals of the Fifth Circuit in its decision points out (R. 178):

"... Results which are incongruous or absurd are to be avoided. Where a particular construction of a statute will occasion great inconvenience or produce inequality and injustice, that view is to be avoided if another and more reasonable interpretation is present in the statute. In the construction of a legislative measure, statutes in pari materia, amendatory acts, and their legislative history may be examined. These rules are the primary guides to our solution of the problem before us."

and the opinion itself (R. 178) cites the various cases of the Supreme Court of the United States which they consider in reaching this conclusion.

What the Supreme Court has said and the Fifth Circuit has said was also said about this bill in the Senate Report and by President Franklin D. Roosevelt in his message to the Congress included in the House Report.

"... and, third, it must impose on honest industrial enterprise no hardship which is unnecessary or unjustified in the public interest."

Dunn—687, Amended Report, Senate, Rep. No. 152 75th Congress, 1st Sess.

"No honest enterpriser need fear that because of the passage of such a measure he will be unfairly treated. He would be asked to do no more than he now holds himself out to do..."

Dunn—267, House Report 74th Congress, 2d Sess., Message from President Franklin D. Roosevelt, March 22, 1935.

IV

RECENT LEGISLATION

While this brief was being prepared the Congress passed "The Food Additives Amendment of 1958" The definition of food additives appears in Sub-section (s) of Section 2 and contains among other things the following wording:

"The term 'food additive' means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food;" etc.

Public Law 85-929, Sec. 2(s), H. R. 13254, 85th Congress, 72 Stat 1784.

This legislation certainly puts at rest all references in

the Petitioner's brief as to the effect of the Court decision on sweeteners, oleomargarine and other substances added in other foods. This legislation provides that the Secretary can establish a regulation, prescribe the conditions under which such additive may be safely used. Both the Senate Report and the House Report explain the concept of safety as follows:

> "The concept of safety used in this legislation involves the question of whether a substance is hazardous to the health of man or animal. Safety requires proof of a reasonable certainty that no harm will result from the proposed use of an additive. It does not—and cannot—require proof beyond any possible doubt that no harm will result under any conceivable circumstance.
>
> "This was emphasized particularly by the scientific panel which testified before the subcommittee. The scientists pointed out that it is impossible in the present state of scientific knowledge to establish with complete certainty the absolute harmlessness of any chemical substance."
>
> House Report 2284, pp. 4, 5, 85th Congress, 2d Sess.
>
> Senate Report 2422, p. 6, 85th Congress, 2d Sess.

It will be noted here that as the Supreme Court had pointed out in the Lexington Mill case, supra, and the Woods case, supra, and as the Court of Appeals for the Fifth Circuit pointed out in this case, the Congress pointed out clearly the impossibility with complete certainty to establish absolute harmlessness of any chemical substances and said on page 2 of the Senate Report:

> "Conscious of the fact that any substance or, for that matter, any particular food known to be good for the

health of human beings can be deleterious to the health of an individual who insists on consuming inordinate amounts of it, . . ."

and goes on to say that to eat a pound of salt or drink four gallons of pure water in an hour would be harmful and explains that the testimony would be to determine whether or not a particular additive used in a specific percentage of relationship to the volume of the product to which it might be added should be that of reasonable certainty in the minds of competent scientists that the additive is not harmful to man or animal. Thus, it will be seen that Congress did not use "harmful" in an absolute sense. The previous departmental canon of construction of "malum in uno, malum in omnibus" is erroneous. Page 3 of the Senate report uses the expression "'safe for humans and animals when used in or within certain quantitative limits." On page 4 of the same Report—"An additive may be shown to be safe either by means of scientific procedures (including a review of existing scientific literature) or, in the case of substances in use prior to January 1, 1958, also by means of experience based on common use in food. And on page 5 states:

"The principal examples of both intentional and incidental additives are substances intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food."

Under the Secretary's present construction, even though the research referred to in H. R. 7732 has been completed and a color with a far greater safety factor than FD&C Red No. 32 has resulted therefrom, this new color could not be certified. A continuation of this construction would be to maintain in the coal-tar area the same unworkable and obsolete principle of utter exclusion that Congress has finally expunged. Affirmation by this Honorable Court of the Fifth

Circuit position is not going to cause any deep-seated or radical change since these changes have already been required by legislation. It would be absurd to say it can be allowed inside the orange and not on the outside and it was pointed out by the Court of the Fifth Circuit even before this new legislation:

> "Such a construction would be an unwarranted discrimination, not so much against the coal-tar color and the manufacturers of it, but against that important segment of the orange producers who are economically dependent upon it. The construction of the Secretary results, or may result, in inequality and injustice. There is, we think, a more reasonable interpretation in the Act." (R. 181)
>
> Florida Citrus Exchange et al vs. M. B. Folsom, 246 Fed. 2d 850

This reasonable construction authorized the Secretary to construe "harmless", taking into consideration the use and quantity, and to set tolerances or safety factors at a level that would not endanger the public health or to certify for limited use.

CONCLUSION

For the foregoing reasons we respectfully submit that the judgment of the Court below should be affirmed.

Respectfully submitted.

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PROOF OF SERVICE

I, James Hardin Peterson, attorney for Florida Citrus Exchange and all other Respondents except Frank R. Schell, and a member of the bar of the Supreme Court of the United States, hereby certify that on the ..... day of October, 1958 I mailed Air Mail, postage prepaid, five copies of the attached brief to:

HONORABLE J. LEE RANKIN
Solicitor General
Department of Justice
Washington 25, D. C.

HONORABLE WILLIAM W. GOODRICH
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IN THE
SUPREME COURT OF THE UNITED STATES

October Term, 1958

No. 27

MARION B. FOLSOM, SECRETARY OF HEALTH, EDUCATION AND WELFARE
Petitioner

versus

FLORIDA CITRUS EXCHANGE, FRANK R. SCHELL, ET AL
Respondents

REQUEST FOR ORAL ARGUMENT

The Respondents, other than Frank R. Schell, by their undersigned attorney, respectfully request oral argument.

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In the Supreme Court of the United States

OCTOBER TERM 1958

No. 27

MARION B. FOLSOM, Secretary of Health, Education and Welfare,
Petitioner

-vs-

FLORIDA CITRUS EXCHANGE, et al,
and
FRANK R. SCHELL,
Respondents.

BRIEF OF RESPONDENT FRANK R. SCHELL

• • • •

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F&DA continued, without any change whatever, the practices followed prior to enactment of the 1938 Act; testified in 1939 that the word "harmless" was used in its "relative" sense and F&DA empowered and directed to fix tolerances for coal-tar colors; recertified in 1939 all colors previously certified and, still in 1939, certified Red 32 and fixed tolerances for poisons and deleterious substances found in coal-tar colors.

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Chronic Toxicity Studies On Food Colours, by M. G. Almark, H. C. Grice and W. A. Mannell, Canadian Food and Drug Laboratories, Department of National Health and Welfare, Canada; published June, 1956, "The Journal of Pharmacy and Pharmacology, 1956, 8, pp. 417-424" App. 1-8; ..... at 33, 34, 35

ERRATA IN RECORD

R. 87: Re Experiment 9, first par., line 2, "dilation" should read "dilution".

R. 141, 2nd complete par., line 11: "710/0", should read "7/100".

R. 146, 4th par., reads:

"On January 19, he said the administration would open formal hearings *on the subject of whether orange color with coal-tar dyes.*";

whereas the same should read (see correct quotation of omitted language at R. 147):

"On January 19, he said, the administration would open formal hearings *on the subject of whether orange growers would be allowed to continue tinting their fruits orange color with coal-tar dyes.*" (Emphasis supplied).

Regrettably, neither the record herein, or in the Court below, shows the page where F&DA's Ex. 4 (Hearing of January 19, 1954) was formally offered in evidence (at p. 37 of the Transcript of Record of Hearing held on January 19, 1954). Ex. 4 was offered for identification at R. 205, and at R. 240 there appears the Reporter's note that it was offered by the Government on that date. Where required by Rule 40 (2) we have used R. 205 as the page reference.

Abbreviations Used

In this brief the following abbreviations and designations have been used:

"Secretary" refers to Hon. Marion B. Folsom, Secretary of Department of Health, Education and Welfare and his successor in office.

"Respondent" refers to Frank R. Schell.

"R____" refers to pages of Transcript of Record in this Court.

"Ap.____" refers to pages of Appendix to this brief.

"U.S.D.A." refers to Federal Dept. of Agriculture.

"F&DA" refers to Federal Food and Drug Administration.

"The Act" refers to 1938 Food, Drug and Cosmetic Act.

"The 1906 Act" refers to 1906 Food and Drug Act.

"Color Added" refers to process for coloring oranges with coal-tar color.

"Red 32", or similar words, refers to the coal-tar color FD&C Red No. 32 or other certified coal-tar colors.

"Dunn,_____" refers to pages in work titled "Federal Food, Drug and Cosmetic Act." (1938) by Charles Wesley Dunn, being a compilation of official records of the Congress re food and drug legislation over the years 1933 to 1938, both inclusive.

"Ppm" refers to ratio of parts of color per million parts of food colored therewith.

"Coal-tar Color Regulations" refers to F&DA Regulations re certified coal-tar colors, promulgated in 1940 and titled "Coal-tar Color Regulations, S.R.A., FDC 3, "(21 C.F.R. 135, part 9)."

In the Supreme Court of the United States

OCTOBER TERM 1957

No. 27

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Petitioner

-vs-

FLORIDA CITRUS EXCHANGE, et al,
and
FRANK R. SCHELL,
Respondents.

Brief of Respondent Frank R. Schell

STATEMENT OF THE CASE

We are unable to accept the statement set forth on pages 5-14 of Petitioner's Brief and under various subheads will set forth what we conceive to be the factual matters to be considered by the Court in the disposition of this cause.

These matters will be presented under subheads as follows:

(1) The Artificial Coloring of Oranges and the Importance Thereof to the Citrus Industry.

(2) History of Color-Added Process and Proceedings with regard thereto.

(3) Statutes Involved.

(4) The Tests Upon Which the Secretary Based the Order do not Justify or Substantiate the Order.

(4)(a) New Legislation.

Following the material presented under the above subheads, we will present the issues and our arguments thereon under the subheads:

(5) Questions Presented.

(6) Argument

(a) The issues in this case.

(b) The language of the Act.

(c) The legislative history of the Act.

(d) Contemporaneous administrative construction of the Act.

(e) F&DC Red No. 32 is harmless and suitable for use in coloring oranges under the law and facts in this case.

(f) The Circuit Court of Appeals of the Fifth Circuit correctly decided this cause.

(g) Conclusions.

The fundamental facts in this case are that the Secretary of the Department of Health, Education and Welfare decertified certain coal-tar colors that are used in the Color Added process for coloring oranges.

The tests conducted by the Food and Drug Administration demonstrated that when these colors were fed to dogs in massive doses they produced adverse effects. The F&DA, however, admitted frankly that in the amounts used to color oranges there was no evidence whatever that such colors would or could produce any adverse effects.

The Secretary, however, takes the position that the Food, Drug and Cosmetics Act of 1938, hereafter referred to as the 1938 Act, does not authorize him to restrict the use of such colors to a particular purpose or limit the amount that may be used for such purpose

and that having established that the colors are toxic in the smallest degree he has no alternative except to decertify such colors and make their use for any purpose and in any amount unlawful.

The fundamental issue of law in this case revolves around the word "harmless" as the same appears in Section 406 (b) of the 1938 Act.

The Secretary takes the arbitrary position that "harmless" as used in the 1938 Act must be construed in its *absolute* sense, that is, that before any color may be used to color oranges it must be *absolutely harmless* in any and all amounts.

We take the position that the word harmless as the same is used in the 1938 Act is to be construed in its *relative* sense, that is, that a color shall be certified by the Secretary if the same is harmless for the purpose for which it is intended and in the amounts used for such purpose.

Section 406 (b) of the 1938 Act mandatorily requires the Secretary to certify coal-tar colors that are "harmless and suitable for use in food" and it is our contention that the colors in controversy are harmless and suitable for use in coloring oranges, and the F&DA admits as much but refuses to certify such colors for such purpose.

The Circuit Court of Appeals held that under the facts in this case is was the duty of the Secretary to certify FD&C Red No. 32 (one of the colors in controversy) for use in coloring oranges.

From that judgment the Secretary seeks review by this Court.

THE ARTIFICIAL COLORING OF ORANGES AND THE IMPORTANCE THEREOF

In explanation of what might otherwise be deemed

an unnecessary digression, we respectfully submit our conviction that a consideration of the issues in the instant case cannot be properly approached without an appreciation and consideration of the history of the coloring problems of the orange industry and what has been done in the past to solve them.

These problems stem from the fact that, unfortunately, ***no horticulturist has ever been able to make the exterior color of an orange conform to inner maturity as the orange ripens, and all varieties - early, mid-season and late - continue to attain their optimum color during the few months of cold weather, as did their ancestors along the shores of the Mediterranean.***

U.S.D.A. succinctly and effectively stated the whole problem in its Yearbook for 1932 (pp. 134-137):

> *"Some of the early Fall varieties of oranges and grapefruit ripen while the fruit is still green in color. Later varieties that mature in the Spring or Summer assume the color of full maturity during the winter while the fruit is still immature, but when warm weather occurs the rind may turn green again. Thus while the edible part of the fruit ripens, there is a 'regreening' of the rind.* Grapefruit growing inside of densely foliated trees never develops full color, although some of the best flavored fruit is produced there. *There is therefore no definite relation between flavor or maturity and the color of the fruit while on the tree. However, there is a very significant relation between the color of the fruit offered for sale, and the price that it will bring, and citrus fruit producers have always faced the problem of making the color of ripe fruit match its flavor."* (Emphasis ours.) (R. 122-123).

The Ethylene Gas Process For Coloring Citrus Fruit

In the year 1923 Dr. Frank E. Denny, U.S.D.A. obtained and dedicated to the public Letters Patent of the United States No. 1,475,938, entitled "Method of Coloring Citrus Fruits," which process is generally known as the "ethylene gas process." This Patent's single claim recites:

> "A new and useful method of coloring citrus fruits, consisting in bringing ethylene gas into contact with green citrus fruits, and maintaining that contact at a temperature as low as 55 degree F., and below 85 degree F."

The process was so successful that within a comparatively short space of time it was in use in practically every citrus packing house in the country.

While the ethylene gas process was an important aid to the development of the orange industry, nevertheless the process has its limitations and imperfections. Without expanding this subject, it may be said that the use of ethylene gas is far from a simple procedure, its proper application requiring experts in that field, otherwise the fruit may be weakened, resulting in an increase in "stem and rot" and other forms of decay. At best the fruit, depending on various factors, may have to remain in the coloring rooms for 36 to 96 hours. This time alone is a detrimental factor.

Further, it is impossible to secure a uniform coloration. As stated in the Yearbook of Agriculture for 1932, page 136:

> "Experience has shown that few citrus crops react alike to the coloring process, since growing conditions have a marked influence on the rate of coloring. Variable weather conditions and variations in the condition of the fruit itself from time to

time prevent adoption of a standardized coloring procedure."

The Color-Added Process For Coloring Citrus Fruit

These considerations, among other, prompted the development of what came to be known, in 1934, as the "Color Added" process (those words being the declaration of added color required to be stamped on the peel of oranges so colored).

The Color Added process constitutes merely an improvement on the prior coloration practices, the only variation requiring mention here being the use of a minute amount (4 parts of color per million parts of the whole orange) (R. 141, infra) of an oil soluble, water insoluble, certified food color, with which the very thin (1/1000 inch) outer layer of waxy and oily constituents of the peel are impregnated by spraying or pouring on, or immersing oranges in, the coloring solution, for a period of some three minutes

The food color used does not penetrate beyond the oil cells in the thin outer cuticle of the orange, and is physically incapable of entering and coloring the white portion of the peel or rag which are oil resistant and water absorbing.

Importance Of Color Added Process To Citrus Industry

The use of the process is of vital importance to the industry - not only from a financial but also from a production viewpoint. This is well established by the following production figures for oranges, showing the production, in million of boxes, in California (where Color Added was not used commercially until 1957) and in Florida and Texas (where it went into use in 1934) for the years 1923-24 (last year before the ethylene gas process went into general use in all citrus producing States); in 1934-35 (the year in which

the Color Aded process went into general use in Florida and Texas); in 1944-45 (ten years after the use of Color Added in those two States became general), and in 1947-1948 (Annual Summary, 1955 Agricultural Marketing Service, Joint U.S.D.A. - Florida Crop and Livestock Reporting Service, Florida Department of Agriculture, p. 6):

Orange Production (In Thousands of Boxes)

Year	*Florida*	*Arizona California*	*Texas*	*Other*	*Total*
1923-1924	13,150	24,234	6	295	31,819
1934-1935	15,600	45,217	650	521	61,988
1944-1945	42,800	61,650	1,150	360	109,210
1947-1948	58,400	46,610	5,200	300	110,510

The Congress has formally held that the artificial coloring of oranges with certified coal-tar food colors is an "economic necessity" to the orange industry of those States, in these words *(H. R. No. 1982, 84th Congress 2d Session, March 29, 1956, p. 2; Senate Report No. 2391, 84th Congress 2d Session, June 29, 1956, p. 1)*:

> *"This practice has become an economic necessity for a major segment of the orange industry,* since large quantities of oranges grown in Florida and Texas would meet with strong consumer resistance if they were not artificially colored. Oranges so colored are plainly stamped 'color added' so that the buying public is fully appraised of the fact." (Emphasis supplied).

This finding by the Congress was premised upon the testimony and statements before the House Com-

mittee concerned, found in the transcript thereof, as hereinafter quoted.

In the report of "*Hearing Before A Sub-Committee Of The Committee On Interstate And Foreign Commerce, House Of Representatives, 84th Congress, 2d, Session, on H.R. 7732, February 10, 1956,*" we find the following last paragraph in the statement of Mr. John T. Lesley, General Manager, Florida Citrus Exchange, Tampa, Florida, a co-operative association of citrus growers and Florida's largest shipper of oranges, handling 8 to 10 million boxes of fresh fruit in interstate commerce annually, from packing houses located in every producing area of Florida, which statement appears *at page 12 of said report:*

> "During the 20 years we have been color-adding oranges, it has become such an accepted practice that non-colored oranges can be sold to advantage only along a limited area of the Eastern seaboard. *It is our considered opinion as Florida's largest fresh fruit marketers, that if the color-added process is banned, the State's fresh fruit marketing will be thrown into complete chaos.* Our major markets - accustomed to colored fruit - will resist the paler fruit with the inevitable result that the seaboard markets will be overloaded, causing terrific price declines to the detriment of the Florida growers. For these reasons we wholeheartedly endorse the pending legislation." (Emphasis supplied).

Testimony as to the value of and necessity for such artificial coloring of oranges is likewise set forth, in that Report, by Mr. Roscoe Skipper, Vice President and Sales Manager of Snively Groves, Inc., Winter Haven, Florida (pp. 12-13 of Report) and of Mr. Herman J. Heidrich, of the firm of Herman J. Heid-

rich and Sons, of Orlando, Florida, largest independent shipper of citrus fruits in Florida, who, referring to the possibility of shipping regreened Valencia oranges without artificial color, said (pp. 14-15): *"Marketing in this condition would be suicidal."* (Emphasis supplied).

At page 5 of that Report, from Mr. Austin E. Anson, Executive Manager, Texas Citrus and Vegetable Growers and Shippers, Harlingen, Texas, we find the following statements:

"* * * FD&C Red No. 32 has been used on all of the oranges shipped from the State of Texas for the past 18 years. This is necessary by reason of the fact that our soil and climatic conditions do not permit the oranges to mature with a natural orange color, and it is necessary to process the oranges and use an artificial coloring procedure using FD&C Red No. 32.

* * *

"So far as the growers and shippers of Texas oranges are concerned *there is no substitute for this coloring process* at this time, and *until such time as a satisfactory substitute is developed and made available that will produce a color in line with the trade's requirements we will be unable to market our oranges,* as the trade territory supplied by Texas positively refuses to purchase any but well orange-colored oranges." (Emphasis supplied).

Regulation Of Color Added Process

The Color Added process went into commercial use in 1934, between biennial sessions of the Florida legislature. In May, 1935, the Florida Legislature, at the instance of the citrus industry, enacted what was known as Florida's "Color Added Act" (Florida Statutes 1935, Chapter 16.81, Secs. 1-15).

As to Maturity Standards, the Color Added Act of 1935 required a minimum solids-acid ratio of 8.5 to 1; a minimum percent of 8.5 solids in the juice, and a minimum juice content of 4.5 gals. per standard packed box.

Those standards have been raised, from time to time, always at the instance of the Florida citrus industry, until the present standards are as follows (Florida Statute 1957, Secs. 601.75 - 601.84):

Comparative Maturity Standards For Florida Oranges
Throughout The Calendar Year

Nature of Test	*Aug.* 1-*Oct.* 31	*Nov.* 1-*Nov.* 15	*Nov.* 16-*July* 31
Minimum Percent Soluble Solids			
Federal Test (F&DA)	.0	.0	.0
Non-Colored	9.0	8.7	8.5
*Color Added	9.2	9.0	8.7
Minimum Percent Citric Acid			
Federal Test (F&DA)	.0	.0	.0
Non-Colored	0.4	0.4	0.4
Color Added	0.5	0.5	0.5
Minimum Ratio of Solids to Acid*			
Federal Test (F&DA)	8.0	8.0	8.0
Non-Colored	9.5	9.65	9.75
Color Added	9.4	9.5	9.65
Minimum Juice Content (Gals. per box)			
Federal Test (F&DA)	.0	.0	.0
Non-Colored	4.5	4.5	4.5
Color Added	5.0	5.0	5.0

*When the percentage of soluble solids is higher, the ratio of soluble solids to acid may be lower, as, for example, when soluble solids are 9.2 percent, the ratio of solids to acid must be not less than 9.4 to 1, but when the soluble solids are but 9.0 percent, the ratio must be 9.65 to 1.

HISTORY OF COLOR ADDED PROCESS AND PROCEEDINGS WITH REGARD THERETO

The Color Added process for enhancing the varietal color of mature oranges, by impregnating the peel thereof with a minute amount of a certified oil soluble, water insoluble, food color, was perfected in 1933, (R. 122) but due to opposition of Mr. Walter G. Campbell, then Chief of F&DA (R. 125-130) the process did not go into commercial use until the Fall of 1934, after a ruling by the Solicitor for Department of Agriculture dated February 28, 1934, settled the points of law concerned and overruled Mr. Campbell's contentions (R. 125).

We respectfully call the Court's attention to the following:

(1) The opposition of F&DA, under the direction of Mr. Walter G. Campbell, then Chief of F&DA, to *any* use of *any* coal-tar food color in *any* food, particularly the coloring of the peel of oranges. (R. 124-130)

(2) The early (1933-1937) attempted total prohibition of use of the Color Added process, sought by the Chief of F&DA, alleging the use of color to deceive the consumer, which charge was completely refuted during a series of Department of Agriculture hearings had in 1934, 1935, 1936 and 1937 (R. 124-127).

(3) The attempts of Mr. Campbell to procure from the Congress legislation that would enable F&DA to outlaw the Color Added process, by withholding certification of food colors indispensable to the operation thereof and the defeat of all such attempts (R. 127-130).

(4) The final agreement of Mr. Campbell and

Honorable J. Hardin Peterson, then Representative from the First Congressional District of Florida and now counsel in the companion case, relating to terms of the Act (R. 130) and

(5) The subsequent drafting of amendments to the pending legislation by agreement had between Mr. Campbell on the one hand, and Mr. Peterson and counsel for this Respondent on the other hand, (which amendments were finally incorporated in Section 402 (c) and Sections 406 (a) and 406 (b) of the 1938 Food, Drug and Cosmetic Act as enacted) (R. 130) each of said amendments (as then concurred in by the then Chief of F&DA) having been enacted by the Congress for the specific purpose and with the specific intent of preventing F&DA destroying the Color Added process by denying certification to colors indispensable to the operation therof, which enactments by the Congress F&DA now seeks to contravene by removing from the list of certifiable coal-tar colors every such color that might be so used for coloring oranges.

Following enactment of the 1938 Act as thus amended, there was no further interference with Color Added by F&DA until 1953 (R. 132-133). From 1937 until now, there was no complaint to (or by) F&DA that the process was being improperly operated or improperly used or that the States of Florida and Texas were not properly policing the use of the process.

In June, 1950, *the color FD&C Violet No. 1 was added to the list of certifiable coal-tar food colors, despite adverse effects upon test animals when fed that color in large amounts,* as to which F&DA said, in the Order allowing certification (Finding of Fact 13, 15 Fed. Reg. 3517, June 7, 1950):

"The amount of color fed the animals in the test referred to in Finding No. 12 was far in excess of the amounts that any human might obtain as a result of food colored with FD&C Violet No. 1".

From brief filed *in the Departmental proceedings* by Counsel for Chase and Company and Mr. Randall Chase of Sanford, Florida, we now quote the follownig (R. 57):

"*By letter dated October 13, 1952,* addressed to Mr. Randall Chase, *the Associate Commissioner of Food and Drugs stated* in part:

"'Let me say at the outset that this Administration is in agreement with your conclusior. that the use of added color on oranges is inherently deceptive and is contrary to the interests of both consumers and producers.'

"We are in entire accord with that administrative position. *We are in disagreement, however, with the view apparently taken at that time that the legislative history of the Act requires a conclusion that the law does not ban the use on oranges of such dyes* as create an economic cheat upon the consumer." (Emphasis supplied.)

Thus we find that, as late as October 13, 1952, F&DA conceded its admission of knowledge of the fact that the legislative history of the Act disclosed that, as hereinbefore set forth (p. 13 supra) it was the intent of the Congress, in enacting amendments thereto, to preclude any attack upon the use of Red 32 for coloring oranges.

On March 18, 1953, a conference was held in Washington pursuant to call by F&DA, to discuss the alleged toxicity of the colors FD&C Orange No. 1, FD&C Orange No. 2, FD&C Red No. 32, FD&C Yellow No. 3 and FD&C Yellow No. 4 (R. 226).

The first mentioned Orange No. 1 is a water soluble color as to which a complaint had been received "several years" before (R. 199) being the only complaint known to F&DA as to any adverse effects upon any human being from certified coal-tar colors (R. 211-212). Orange No. 1 is of the proper hue to color oranges, but is a water-soluble color, hence will not dissolve in and color the oily and waxy constituents of the peel of an orange, but F&DA thereafter suggested (R. 149) that such water-soluble colors be "adapted" to the coloring of oranges.

The other four colors are oil-soluble colors and are the only colors ever certified that will color the peel of oranges.

(FD&C Orange No. 2 and Red No. 32 are the oil-soluble colors sought to be decertified in the instant case. Notice of final Order deleting FD&C Yellow No. 3 and FD&C Yelow No. 4 from the list of certifiable food colors, *without any hearing thereon unless objected to within 30 days, a clear-cut evasion of the procedure required by Sec. 701 (e)* of the Act, was published on May 4, 1957 (22 F. R. 3173) but was strongly objected to and action thereon was postponed by notice published in Federal Register for August 17, 1957, p 6613.

The attention of the Court is respectfully directed to the fact that no delisting action has been taken by F&DA against any color save those that will color an orange or which F&DA mistakenly believes might be "adapted" to the coloring of oranges.)

F&DA then, in 1953, initiated a series of abbreviated tests of Red 32, which ran for 173 days only and, on the strength of erroneous conclusions premised upon results which, insofar as concerns tests at 100 and 400 ppm, we show to be incredible (p. 32-39 infra.),

repudiated the results of a previous series of tests made by its own pharmacologists over a period of six years (1938-1944) (Ex. 4, R. 205, 253, 254), and informed the color manufacturers that F&DA proposed to delete Red 32, Orange 2 and Orange 1 from the list of certifiable dyes (R. 226).

Notice of hearing re proposed delisting of the three colors concerned was published in the Federal Register for December 19, 1954 (R. 37).

On January 1st, 1953 *Commissioner George P. Larrick,* in an interview with a Washington newspaperman, *identified the purpose of the hearing* to be held on January 19, 1954, as being the determination of *"whether orange growers would be permitted to continue tinting their fruits orange color with coal-tar dyes."* (R. 146-147).

When this Respondent learned, on December 18, 1953, of the real purpose of the hearings, and especially after the confirmation by Commission Larrick on January 1, 1954, it was then far to late to employ counsel and inform them as to the ramifications of a highly technical subject matter and be properly represented at the hearing on January 19, 1954, and this Respondent necessarily was not represented (R. 117-118). Also, feeding tests at proper levels, having some relation to public health, and analyses to determine the color content of all foods colored with the three colors, would have required a minimum of three year's time.

At the hearing on January 19, 1954, while admitting (R. 211-212) that they had no information as to harmfulness of the colors at "levels of ordinary normal conditions of use", F&DA presented data which proved only that test animals can be made ill by the colors when fed amounts thereof which are vastly in excess

of normal uses in foods, a result that would, of course, follow from like excessive consumption of any other substance possible of being ingested by man. (R. 205. 239-259).

Some data was presented by counsel for the color manufacturers, from the Florida Citrus Commission, as to amount of added color deposited in the peel of Color Added oranges (4 parts of color per million parts of whole oranges); in the juice, (7/100 of 1 ppm) and marmalade (1.8 ppm) when made from Color Added oranges (R. 225). No other presentations by Respondent or the citrus industry were possible, for reasons stated.

On December 22, 1954, Notice of Proposed Rule Making was signed by an Assistant Secretary. On December 30th said Notice of intent to delete the coal-tar colors FD&C Orange No. 1, Orange No. 2 and Red 32 from the list of certifiable colors, was published in the Federal Register, pp. 9352-53; R. 39.

This Respondent, on March 5, 1955, presented his Petition to Intervene, in his own name, along with Exceptions and Brief and Petition to reopen taking of testimony (R. 116-151) *all within the required time for pleading to the proposed Order.* The Exceptions, Brief and Petition presented matters and things that were self-evidently important and necessary to any proper consideration of the proposed Rule Making. (R. 116-119).

Respondent's pleadings were admitted to the record but his Petition to reopen the proceedings, so as to give Respondent and the Florida citrus industry their day in Court, was allegedly denied by a notation on the margin of the Record (p. 134, 140, 145) but no information thereof was had by Respondent until receipt of copy of printed record in the Court below.

On November 10, 1955, the Secretary issued the final order appealed from. The Order (R. 158) was published on November 16, 1955 (20 F. R. 8493) and on that same date the Department published its official Press Release HEW C-81, November 16, 1955, from which we quote:

> *"FDA Commissioner George P. Larrick said the three colors involved are harmless in the amounts ordinarily consumed in foods, but* recent scientific investigation shows they are *not harmless when fed in large amounts.* (Emphasis supplied).
>
> "The colors involved are FD&C Orange No. 1, FD&C Orange No. 2, and FD&C Red No. 32. Orange No. 1 has been widely used in candy, cakes, cookies, carbonated beverages, desserts and meat products, particularly hot dogs. Orange No. 2 and Red No. 32 are the dyes which have been used in coloring the outer skin of oranges."

There followed the proceedings in Fifth Circuit Court of Appeals and the decision of July 12, 1957, which held (Chief Judge Hutcheson dissenting) (1) that the word "harmless" should be construed in accordance with the rule laid down by the Supreme Court in *U. S. vs. Lexington Mill & Elevator Co.* (232 U. S. 399); (2) that the Secretary has the power to fix maximum limits of use (tolerances) for coal-tar food colors, and (3) that the Secretary has and has exercised the power to limit the use of a specific color to one specific usage, and ordered the Secretary to proceed accordingly (R. 168-187).

F&DA filed their petition for rehearing, which was denied by memorandum decision, per curiam, on August 28, 1957, Chief Judge Hutcheson again dissenting (R. 192).

The mandate issued on October 12th, 1957 and F&DA are now prosecuting their Petition to this Court.

We respectfully submit that, in view of the foregoing, the following points are clearly established: (1) the economic necessity for the Color Added process; (2) that oranges so colored are of superior quality; (3) that the "Color Added' label is the guarantee of the States of Florida and Texas that oranges so colored are of superior quality; (4) that such oranges are, in fact, completely harmless even if the entire peel of the orange be eaten; (5) that such harmlessness is admitted by F&DA; (6) that, the attempt to prohibit the use of Red 32 for coloring oranges contributes exactly nothing to the protection of public health; that, accordingly, there was no foundation in fact for the effort of F&DA to outlaw the Color Added process by denying certification to coal-tar food colors indispensable to the operation of that process.

ERRORS IN PETITION FOR CERTIORIARI

By permission of the Solicitor General and of Commissioner Larrick of F&DA and Assistant General Counsel Goodrich of HEW, we recited at pp. 17-25 of our Brief In Opposition to Certioriari, the details of research work done in good faith, by the industry, to fomulate a new oil-soluble color known as Citrus Red No. 2, at a cost of some $170,000.00, to be used for coloring oranges. We now complete that recitation by these two statements.

(1) Extraction tests run by the University of Florida Extension Service laboratories at Lake Alfred, Florida, showed that oranges colored with Citrus Red No. 2 contained, in the outer peel thereof, 01.133 parts of color per million parts of the

whole orange, as compared to 4 ppm. for F&DC Red No. 32.

(2) Application for certification of Citrus Red No. 2 was duly filed and has been rejected on the alleged grounds that it is a toxic substance, not "harmless" within the meaning of Sec. 406 (b) although pharmacologists of F&DA agree that the "no effect" feeding level is not lower than 1000 ppm. — and that is 882 times the intended use for coloring oranges.

STATUTES INVOLVED

To complete the citation we are quoting, in full, clauses 1 and 2 of Sec. 402 (a), Secs. 402 (c), 406 (a) and 406 (b) of the Act, the Secretary's citation of "pertinent parts" in Petition For Certiorari (p.p. 3-5) having omitted portions which we deem to be not only pertinent but most important.

"Sec. 402. A food shall be deemed to be adulterated—

(a) (1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health; or (2) if it bears or contains any added poisonous or added deleterious substance, except a pesticide chemical in or on a raw agricultural commodity, which is unsafe within the meaning of section 406, or if it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of Section 408 (a); or * * *."

* * *

"(c) If it bears or contains a coal-tar color other

than one from a batch that has been certified in accordance with regulations as provided by section 406; Provided that this paragraph shall not apply to citrus fruit bearing or containing a coal-tar color if application for listing of such color has been made under this act and such application has not been acted on by the Secretary, if such color was commonly used prior to the enactment of this act for the purpose of coloring citrus fruit; Provided further, That this paragraph shall not apply to oranges meeting minimum maturity standards established by or under the laws of the States in which the oranges were grown and not intended for processing (other than oranges designated by the trade as 'packing house elimination') the skins of which have been colored at any time prior to March 1, 1959, with the coal-tar color certified prior to the enactment of this proviso as FD&C Red 32, or certified after such enactment as External D&C Red 14 in accordance with section 21, Code of Federal Regulations, part 9: And provided further, That the preceding proviso shall have no further effect if prior to March 1, 1959, another coal-tar color suitable for coloring oranges is listed under section 406." (21 U.S.C. 342)

* * *

"Sec. 406 (a) Any poisonous or deleterious substance added to any food, except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice shall be deemed to be unsafe for purposes of the application of clause (2) of section 402 (a); but when such substance is so required or cannot be so avoided, the Secretary shall promulgate regulations limiting the quantity therein or thereon to such

extent as he finds necessary for the protection of public health, and any quantity exceeding the limits so fixed shall also be deemed to be unsafe for purposes of the application of clause (2) of section 402 (a). While such a regulation is in effect limiting the quantity of any such substance in the case of any food, such food shall not, by reason of bearing or containing any such added amount of such substance, be considered to be adulterated within the meaning of clause 1 of section 402 (a). In determining the quantity of such added substance to be tolerated in or on different articles of food the Secretary shall take into account the extent to which the use of such substance is required or cannot be avoided in the production of each such article, and the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances.

"(b) The Secretary shall promulgate regulations providing for the listing of coal-tar colors which are harmless and suitable for use in food and for the certification of batches of such colors, with or without harmless diluentes" (21 U.S.C. 346).

Public Law 85-929
85th Congress, H. R. 13254
September 6, 1958
72 Stat. 1784.

(Excluding Sec. 409 (g) (1) and thereafter of Sec. 4, and Secs. 5-8, inc., not deemed pertinent here).

AN ACT

To protect the public health by amending the Federal Food, Drug and Cosmetic Act to prohibit the use in food of additives which have not been adequately tested to establish their safety.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Food Additives Amendment of 1958".

Sec. 2. Section 201, as amended, of the Federal Food, Drug, and Cosmetic Act is further amended by adding at the end of such section the following new paragraphs:

"(s) The term 'food additive' means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use; except that such term does not include—

"(1) a pesticide chemical in or on a raw agricultural commodity; or

"(2) a pesticide chemical to the extent that it is intended for use or is used in the production, storage, or transportation of any raw agricultural commodity; or

"(3) any substance used in accordance with a sanction or approval granted prior to the enactment of this paragraph pursuant to this Act, the Poultry Products Inspection Act (21 U.S.C. 451

and the following) or the Meat Inspection Act of March 4, 1907 (34 Stat. 1260), as amended and extended (21 U.S.C. 71 and the following).

"(t) The term 'safe', as used in paragraph (s) of this section and in section 409, has reference to the health of man or animal."

SEC. 3. (a) Clause (2) of section 402 (a), as amended, of such Act is amended to read as follows: "(2) (A) if it bears or contains any added poisonous or added deleterious substance (except a pesticide chemical in or on a raw agricultural commodity and except a food additive) which is unsafe within the meaning of section 406, or (B) if it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of section 408 (a), or (C) if it is, or it bears or contains, any food additives which is unsafe within the meaning of section 409: *Provided*, That where a pesticide chemical has been used in or on a raw agricultural commodity in conformity with an exemption granted or a tolerance prescibed under section 408 and such raw agricultural commodity has been subjected to processing such as canning, cooking, freezing, dehydrating, or milling, the residue of such pesticide chemical remaining in or on such processed food shall, notwithstanding the provisions of section 406 and 409, not be deemed unsafe if such residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice and the concentration of such residue in the processed food when ready to eat is not greater than the tolerance prescribed for the raw agricultural commodity;".

(b) Section 402 (a), as amended, of such Act is further amended by striking out the period at the end thereof and inserting in lieu thereof a semicolon and

the following: "or (7) if it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 409."

(c) The first sentence of section 406 (a) af such Act is amended by striking out "clause (2)" wherever it appears in such sentence and inserting in lieu thereof "clause (2) (A)".

Sec. 4. Chapter IV of such Act as amended by adding at the end thereof the following new section:

"FOOD ADDITIVES

"Unsafe Food Additives

"Sec. 409. (a) A food additive shall, with respect to any particular use or intended use of such additives, be deemed to be unsafe for the purposes of the application of clause (2) (C) of section 402 (a), unless—

"(1) it and its use or intended use conform to the terms of an exemption which is in effect pursuant to subsection (i) of this section; or

"(2) there is in effect, and it and its use or intended use are in conformity with, a regulation issued under this section prescribing the conditions under which such additive may be safely used.

While such a regulation relating to a food additive is in effect, a food shall not, by reason of bearing or containing such an additive in accordanee with the regulation, be considered adulterated within the meaning of clause (1) of section 402 (a).

"Petition To Establish Safety

"(b) (1) Any person may, with respect to any intended use of a food additive, file with the Secretary a petition proposing the issuance of a regulation pre-

scribing the conditions under which such additive may be safely used.

"(2) Such petition shall, in addition to any explanatory or supporting data, contain—

"(A) the name and all pertinent information concerning such food additive, including, where available, its chemical identity and composition;

"(B) a statement of the conditions of the proposed use of such additive, including all directions, recommendations, and suggestions proposed for the use of such additive, and including specimens of its proposed labeling;

"(C) all relevant data bearing on the physical or other technical effect such additive is intended to produce, and the quantity of such additive required to produce such effect;

"(D) a description of practicable methods for determining the quantity of such additive in or on food, and any substance formed in or on food, because of its use; and

"(E) full reports of investigations made with respect to the safety for use of such additive, including full information as to the methods and controls used in conducting such investigations.

"(3) Upon request of the Secretary, the petitioner shall furnish (or, if the petitioner is not the manufacturer of such additive, the petitioner shall have the manufacturer of such additive furnish, without disclosure to the petitioner) a full description of the methods used in, and the facilities and controls used for, the production of such additive.

"(4) Upon request of the Secretary, the petitioner shall furnish samples of the food additive involved, or articles used as components thereof, and of the food

in or on which the additive is proposed to be used.

"(5) Notice of the regulation proposed by the petitioner shall be published in general terms by the Secretary within thirty days after filing.

"Action on the Petition

"(c) (1) The Secretary shall—

"(A) by order establish a regulation (whether or not in accord with that proposed by the petitioner) prescribing, with respect to one or more proposed uses of the food additive involved, the conditions under which such additive may be safely used (including, but not limited to, specifications as to the particular food or classes of food in or on which such additive may be used, the maximum quantity which may be used or permitted to remain in or on such food, the manner in which such additive may be added to or used in or on such food, and any directions or other labeling or packaging requirements for such additive deemed necessary by him to assure the safety of such use), and shall notify the petitioner of such order and the reason for such action; or

"(B) by order deny the petition, and shall notify the petitioner of such order and of the reasons for such action.

"(2) The order required by paragraph (1) (A) or (B) of this subsection shall be issued within ninety days after the date of filing of the petition, except that the Secretary may (prior to such ninetieth day), by written notice to the petitioner, extend such ninety-day period to such time (not more than one hundred and eighty days after the date of filing of the petition) as the Secretary deems necessary to enable him to study and investigate the petition.

"(3) No such regulation shall issue if a fair evaluation of the data before the Secretary—

"(A) fails to establish that the proposed use of the food additive, under the conditions of use to be specified in the regulation, will be safe; *Provided*, That no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal; or

"(B) shows that the proposed use of the additive would promote deception of the consumer in violation of this Act or would otherwise result in adulteration or in misbranding of food within the meaning of this Act.

"(4) If, in the judgment of the Secretary, based upon a fair evaluation of the data before him, a tolerance limitation is required in order to assure that the proposed use of an additive will be safe, the Secretary—

"(A) shall not fix such tolerance limitation at a level higher than he finds to be reasonably required to accomplish the physical or other technical effect for which such additive is intended; and

"(B) shall not establish a regulation for such proposed use if he finds upon a fair evaluation of the data before him that such data do not establish that such use would accomplish the intended physical or other technical effect.

"(5) In determining, for the purposes of this section, whether a proposed use of a food additive is safe, the Secretary shall consider among other relevant factors—

"(A) the probable consumption of the additive

and of any substance formed in or on food because of the use of the additive;

"(B) the cumulative effect of such additive in the diet of man or animals, taking into account any chemically or pharmacologically related substance or substances in such diet; and

"(C) safety factors which in the opinion of experts qualified by scientific training and experience to evaluate the safety of food additives are generally recognized as appropriate for the use of animal experimental data.

"Regulation Issued on Secretary's Initiative

"(d) The Secretary may at any time, upon his own initiative, propose the issuance of a regulation prescribing, with respect to any particular use of a food additive, the conditions under which such additive may be safely used, and the reasons therefor. After the thirtieth day following publication of such a proposal, the Secretary may by order establish a regulation based upon the proposal.

"Publication and Effective Date of Orders

"(e) Any order (including any regulation established by such order, issued under subsection (c) or (d) of this section, shall be published and shall be effective upon publication, but the Secretary may stay such effectiveness if, after issuance of such order, a hearing is sought with respect to such order pursuant to subsection (f).

"Objections and Public Hearing

"(f) (1) Within thirty days after publication of an order made pursuant to subsection (c) or (d) of this section, any person adversely affected by such an order may file objections thereto with the Secretary, specifying with particularity the provisions of the order deemed objectionable, stating reasonable

grounds therefor, and requesting a public hearing upon such objections. The Secretary shall, after due notice, as promptly as possible hold such public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. As soon as practicable after completion of the hearing, the Secretary shall by order act upon such objections and make such order public.

"(2) Such order shall be based upon a fair evaluation of the entire record at such hearing, and shall include a statement setting forth in detail the findings and conclusions upon which the order is based.

"(3) The Secretary shall specify in the order the date on which it shall take effect, except that it shall not be made to take effect prior to the ninetieth day after its publication, unless the Secretary finds that emergency conditions exist necessitating an earlier date, in which event the Secretary shall specify in the order his findings as to such conditions.

THE TESTS UPON WHICH THE SECRETARY BASED HIS ORDER DO NOT JUSTIFY THE ORDER.

The results of F&DA's tests of Red 32 are found in F&DA Exhibit 4 (R. 205, 239 - 259). We have recapitulated these tests and the alleged results thereof in the tabulation next set forth.

Test Animals	Date begun & duration	Level of Administration	Parts per Million	Reported *Effects
Diet Tests				
10 Rats (Ex. 4, R. 205, 239)	1940-102 wks.	0.10%	1,000	2, 4
20 Rats (Ex. 4, R. 205, 240)	1941- 79 wks.	0.10%	1,000	3, 4
5 Rats (Ex. 4, R. 205, 241)	1951- 10 wks.	0.25%	2,500	4
10 Rats (Ex. 4, R. 205, 241)	1951- 26 das.	0.50%	5,000	2, 4
5 Rats (Ex. 4, R. 205, 241)	1951- 12 das.	1.00%	10,000	4
5 Rats (Ex. 4, R. 205, 241)	1951- 7 das.	2.00%	20,000	4
24 Rats (Ex. 4, R. 205, 242)	1952-100 wks.	0.10%	1,000	2, 3, 4
48 Rats (Ex. 4, R. 205, 242)	1952- 20 wks.	0.25%	2,500	2, 3, 4
4 Dogs (Ex. 4, R. 205, 254)	1953- 10 mos.	0.01%	100	2***
4 Dogs (Ex. 4, R. 205, 254)	1953-148 das.	0.04%	400	1, 2, 3, 4
4 Dogs (Ex. 4, R. 205, 254)	1953- 26 das.	0.20%	2,000	1, 2, 3, 4
Dosage Tests				
5 Dogs (a) (Ex. 4, R. 205, 253)	1938- 5-6 yrs.	5/mg/kg/day	200**	0
1 Dog (b) (Ex. 4, R. 205, 253)	1938- 10 mos.	100 mg/kg/day	4,000**	2
	1938- 60 mos.	20 mg/kg/day	800**	0
5 Dogs (Ex. 4, R. 205, 259)	1952-single dose	100 mg		1
10 Dogs (Ex. 4, R. 205, 259)	1952-single dose	100 mg		1

*0-No effect; 1- Diarrhea and related effects; 2-Weight loss or lack of normal gain; 3-Physical deterioration; 4-Increased mortality rate.

**Conversion factor of 40 (authority F&DA, R. 210).

***Excluding one dog which had previously been on a 2,000 p.p.m. diet for 26 days (R. 254).

(a) One dog previously fed 4,000 ppm for 36 days and 800 ppm for 27 days—then this dosage of 200 ppm as shown (R. 253).

(b) This dog received diet containing 4,000 ppm for 10 months, then put on diet containing 800 ppm of color for 60 months (R. 253).

The Tests Run At 1,000 ppm And Higher Added Nothing To Knowledge Of Toxicity Of FD&C Red No. 32.

We have no particular quarrel with any of the tests as made by F&DA except the two tests which were allegedly made at ratios of 100 ppm. (parts per million) and 400 ppm., hereinafter discussed.

As will be noted from the above tabulation all other tests run by F&DA were a mere repetition of tests run by the Food and Drug Administration over a period of five to six years from 1938 to 1944, together with other tests run in 1940 and 1941, except that some of the 1951 tests, notably those run at ratios of 5,000, 10,000 and 20,000 ppm. were made at levels far higher than any employed in 1938-1944.

The tests run by F&DA's own experts, in 1938-1944, had demonstrated conclusively that FD&C Red No. 32 was "harmless" when used at 800 ppm., but was not harmless when fed at 1,000. Tests run by F&DA in 1951 and 1952, at 1,000, 2,500, 5,000, 10,000 and 20,000 ppm. added nothing to knowledge of the toxicity of the colors, proving only that when fed at 1,000 ppm. the color was harmful (as had been proven in 1938-1944) and that the greater the dosage the greater the harm.

The Tests Run By F&DA At Levels Of 100 And 400 ppm. Are Emphatically Refuted By Tests Run By Canadian Scientists in 1955 And By F&DA's Own Experts in 1938-1944.

As to the tests at 100 ppm levels, we would first observe that the alleged result are flatly and emphatically denied by F&DA's own tests, begun in 1938 and running for five to six years into 1944, when five dogs were fed the color at 200 ppm (being double the amount fed in the 1953 short term 100 ppm test relied upon) and of the one dog fed 4,000 ppm for ten months

and, for sixty months thereafter, at 800 ppm, none of the six dogs showing any adverse effects from such feeding. (R. 205, 253 - 254).

We now discuss the two tests, run for this said purpose, at 100 ppm. and 400 ppm. levels.

The results of the 100 ppm test of 1953 are further and emphatically refuted by the Canadian tests at 300 ppm, that ran for 308 days, in 1955, without any adverse effects upon rats so fed. (See App. pp. 1-8).

As to the tests run in 1953, at 400 ppm level, we respectfully submit that this test, also, is refuted by the tests run in 1938-1944 at 800 ppm. when no adverse results attributable to such feeding were had, one dog —(a)— having been fed Red 32 at a 4000 ppm level for 36 days, then at an 800 ppm level for 27 days, then at the 200 ppm level for 5 to 6 years, while the second dog — (b) — was fed at the 4000 ppm level for 10 months, then at the 800 ppm level for 60 months.

We respectfully submit that the most that can be said for the tests at 100 ppm and 400 ppm is that, in view of the prior tests at higher levels which produced no adverse results, the evidence as to those two tests in 1953 is contradictory and most doubtful and inconclusive, falling far short of being that "substantial evidence" which is an indispensable prerequisite to the promulgation of a valid Order by the Secretary, under Sec. 701 (e) of the Act, notwithstanding which that Order reverses a construction of the word "harmless" which had obtained since 1907.

The Evidentiary Value Of All 1953 Tests Is Destroyed By Omission Of Data Indispensible To A Valid Finding

We now respectfully submit that *the evidentiary value* of all of *the* 1953 *tests* but especially the tests on dogs (R. 256-259) run at feeding levels of 100 ppm and 400 ppm, *is completely destroyed by the lack of*

any data whatever as to food consumption by animals on test receiving a ration containing color, as compared to feed consumption by control animals which were on a color-free ration, *absent which data any conclusions premised thereon are sheer guess work — or worse.*

There is no scientific data in the record to indicate how many of the different kinds of ill effects allegedly suffered by these animals could have resulted from malnutrition attributable to refusal, by dogs on test, to eat the food containing the color, but it does not require scientific data to sustain the well-known fact that "emaciation" is an inevitable result and indicator of serious malnutrition. It will be noted from the pathological data (Ex. 4; R. 205, 254, 256) that every one of the dogs receiving various concentrations of Red 32 in their diet, during the 1953 tests, showed "emaciation" in varying degrees, from "slight" to "extreme".

The carcass of the dog that died while on a test diet containing but 100 ppm, above mentioned (No. 16376) showed "extreme emaciation". Significantly, the report also showed "dehydration", indicating refusal of water as well as food, at the end of the test period, before death. This dog had been kept on a diet containing 2,000 ppm of color until it had lost 24 percent of its body weight, in only one month, then put on a color-free diet for about 10 days, during which time it "regained some weight and improved its physical condition" after which it was put on the diet containing 100 ppm of color (Ex. 4, R. 254) which allegedly killed it.

The Court is further respectfully referred to Table I in the report of the Canadian feeding trials with ten rats, (Report p. 419, App. p. 3) where is re-

ported the effect of a diet containing Red 32 at the daily rate of 400 milligrams per kilogram of body weight (approximately 4,000 ppm in the diet, using conversion factor of 10, authority F&DA, R. 209-210). It will be noted that the comparative food consumption is meticulously stated—to tenths of a gram. By reference to data graphs at top of Report p. 420, App. 4, it will be noted that the cumulative food consumption for control and test animals is carefully plotted.

It will also be noted from Table V of Canadian experiments (Report p. 423; App. p. 7) that 12 out of 20 animals on this 4,000 ppm test survived 20 weeks (140) days at this very high feeding level, as compared to 13 surviving controls, while F&DA report on animals fed a ration only one-tenth as high in color (400 ppm) in 1953, shows 100 percent mortality in 120 to 148 days. (Ex. 4, R. 205, 255).

That F&DA fully understood the value and significance of such data is indicated by the statement that: "Each dog was weighed approximately weekly" (Ex. 4, R. 205, 254). Yet, while the tabulation of alleged results (Ex. 4, R. 205. 255) gave exact weight losses for the test animals, *there are no loss or gain weight figures for dogs on the color-free diet* and *there are no data whatever as to food consumption for the dogs on either the color free diet or for the dogs on feeding tests.*

We again respectfully submit that such results from feeding a ration containing 100 ppm and 400 ppm are neither credible or possible of being correct, when appraised in the light of the experiments run by Canadian Food and Drug Directorate at 300 ppm (App. 1-8) and the experiments run by F&DA during the years 1938-1944 (Ex. 4, R. 205, 253, 254) unless

there is some other factor which might explain the injury and death reported.

We respectfully submit our contention that the explanation of such results from 1953 feeding tests, as compared with the results in 1938-1944, will be found in the record of methods used: As to the 1938-1944 tests, the record shows (Ex. 4, R. 205, 253).

> "*Method*: In this experiment, the dogs received the FD&C Red 32, dissolved in corn oil and administered in gelatin capsules daily except Sunday."

Feeding the color in this manner, separate from the animal's food, gave a true indication of the toxicity, or lack of toxicity, of the color, in that, there being no color therein, the offered food created no aversion thereto, or allergy therefor, caused by the odor, taste or effect of the color, and accordingly the animals ate normally when so fed. Any adverse effects would be due solely to the toxicity of the color.

As to the method used in 1953, the record reads: (Ex. 4, R. 205, 254)

> "Method: This dye was fed at levels of 0.2 percent, 0.04 percent and 0.01 percent in a basic diet of ground laboratory chow. Each dog was housed in an individual metabolism cage, was fed and watered daily and had free access to his food. *Each dog was weighed approximately weekly*. A total of 7 females and 3 males were used." (Emphasis supplied)

When so fed, every particle of food contains its equivalent amount of the color, and, if either the odor, taste or effect of the food is unpleasant, the appetite of the animal so fed is adversely effected.

Following the above quoted material, at Exhibit 4, (R. 205, 254, 255) we find this data:

> "Results: The four dogs which were started at

0.2 percent (2,000 ppm) FD&C Red No. 32 in their diet *ate poorly* and two were sacrificed in poor condition at 26 days after having lost respectively 28 percent and 29 percent of their initial weight. *The remaining two,* which had lost respectively 24 percent and 19 percent *were placed on a control diet for about 10 days. During this time they regained some weight and improved their physical condition.* Along with two additional dogs they were placed on a diet of 0.01 percent FD&C Red No. 32. One of these four dogs lost about 60 percent of its body weight and was found dead after 173 days on the 0.01 percent diet. The remaining three have lost some weight but appear in fair condition after nearly 10 months on this level. All four of the dogs on the intermediate level, 0.04 percent (400 ppm) were sacrificed in extremis at 124, 137, 148 and 148 days respectively. All had lost about 50 percent of their body weight. Sporadic but not severe diarrhea was observed during the experiment." (Emphasis and parenthetical matter supplied)

These facts as disclosed by the record, coupled with the absence of any figures whatever as to comparative food consumption as between the control animals that received a color-free diet and the animals fed color mixed in their feed, *are susceptible of but one explanation - that refusal of the dye-containing food, not the toxicity of the dye - was the basic cause for adverse results reported as to the 1953 tests - and the omission of food consumption data was no oversight, nor was it due to inadvertence.*

F&DA attempted to explain away this conflict between the results of the five to six year tests run by F&DA in 1938-1944, and their short term (173 day) tests run in 1953, and further attempted to explain

why the 1938 tests — which showed no injury to animals fed at levels as high as 800 ppm — were not appraised in 1944 as showing, as F&DA now claims those tests show, that Red 32 is not eligible for certification. To that end the following language was used in "Finding of Fact 2" of "Proposed Rule Making" as signed on December 22, 1954 and published in the Federal Register on December 30, 1954 (R. 39 at 40):

> *"Because of advances in knowledge and techniques in the field of pharmacology,* the Food and Drug Administration has initiated new tests *to explore more fully* the toxicity of the certifiable coal-tar colors. *This involves the application of all techniques and procedures now considered necessary to assure proper evaluation.* A number of those tests, *with present-day techniques and procedures,* have been conducted by the Division of Pharmacology of the Food and Drug Administration, using FD&C Orange No. 1, FD&C Orange No. 2 and FD&C Red No. 32." (Emphasis supplied).

Three Respondents in the Deparmental Proceedings filed exceptions to and attacked that language in Finding of Fact 2, showing that the procedures followed in the 1938-1944 tests and in the 1953 tests were substantially identical and that the only thing "new" in the procedures was the new construction being placed on the word "harmless" by F&DA (R. 73, 82, 88-90, 142-143).

In consequence of these attacks upon the verity of the language above quoted in Finding of Fact 2, that Finding, in the final Order appealed from, was changed to read as followed (R. 158 at p. 159):

> "Since that time the Food and Drug Administration has completed additional tests to explore more fully the toxicity of the certifiable coal-tar colors.

A number of additional tests have been conducted by the Division of Pharmacology of the Food and Drug Administration, using FD&C Orange No. 1, FD&C Orange No. 2, and FD&C Red No. 32."

We further respectfully submit that in the light of this record, the results of the experiment conducted in 1953 at levels of 100 ppm and 400 ppm are entitled to neither credence nor consideration, that, as is abundantly clear, such experiments, using such methods, and such incomplete data, destroy the bona fides of F&DA's contentions; that, in these circumstances, the record made in 1953 does not constitute "substantial evidence" that the causative factor for such adverse results was the toxicity of Red 32 itself.

These tests at the most show only that F&DC Red 32 is toxic and will produce adverse effects if given in massive doses.

FD&C Red 32 Is Admittedly "Harmless" As And When Used For Coloring Oranges

The tests, however, fail wholly and completely to show any possible adverse effects from use of FD&C Red 32 in coloring oranges, where the color is used in the ratio of 4 ppm (parts per million).

This has been repeatedly admitted by F&DA as follows:

On November 16, 1955, official news release HEW-C81 of U. S. Department of Health, Education and Welfare, Food and Drug Administration, contained the following statement by F&DA Commissioner George P. Larrick (App. 21).

"The three colors involved are harmless in the amounts ordinarily consumed in foods, but recent scientific investigation shows *they are not harmless when fed in large amounts.*

"The colors involved are FD&C Orange No. 1, FD&C Orange No. 2, and FD&C Red No. 32. Orange No. 1 has been widely used in candy, cakes, cookies, carbonated beverages, desserts, and meat products, especially hot dogs. Orange No. 2 and Red No. 32 are the dyes which have been used in coloring the outer skin of oranges." (Emphasis supplied).

On February 7, 1955, when F&DA's "Proposed Rule Making", dated December 29, 1954, proposing to delist Red 32, had been seized upon as a propaganda weapon directed against the importation of Florida and Texas oranges into Europe, Commissioner George P. Larrick addressed a letter to United States Senator George Smathers of Florida, over the seal of the Department, which letter contained the following statement (R. 135-136):

"The proposal to remove these coal-tar colors, including FD&C Red No. 32, from the list of colors eligible for certification for use in foods results from the requirement of the pure food law that only colors that are harmless are eligible for certification. Recent investigation shows that these colors, when fed in *substantial* amounts, show evidence of toxicity. *There is, however, no evidence that, in the amount used, and in the manner of use, in the coloring of citrus fruit, the product so colored is not safe for human consumption.*" (Emphasis supplied).

In that "Report of Hearing on HR 7732" etc., on February 10, 1956 (p. 8 supra) in his testimony before the House Committee, Commissioner George P. Larrick made the following statement (p. 18 of Report):

"Considering all of the information so far avail-

able—and *bearing in mind particularly the minute amount of this dye likely to enter the human diet as a result of its use on oranges, we cannot say that its continued use on oranges* not intended for processing *would pose a hazard to the public health.*" (Emphasis supplied)

In that same Report in the letter of Secretary Folsom, dated February 13, 1956 (which letter was dated three days after the hearing) we find the following statement (pp. 2-3 of Report):

"While the scientific evidence so far available does not establish what the lowest safe dosage would be to test animals, *neither does it establish a likelihood of injury to man from use of this color on the exterior of oranges at the level of use involved.* ***" (Emphasis supplied)

Summation

We respectfully submit that, in the foregoing, it has been shown:

(1) That data re tests of Red 32 at feeding levels higher than 1000 ppm are irrelevant, immaterial and of no evidentiary value, for the reason that tests run in 1938-1944, and in 1940 and 1941 (p. 31 supra) proved the color Red 32 to be harmful when fed at levels of 1000 ppm., and tests at higher levels, even if correctly run and reported, could prove nothing save that injury to test animals increases as the feeding level is increased beyond 1000 ppm.

(2) That the alleged results of tests of Red 32 at feeding levels of 400 ppm. and 100 ppm. cannot possibly be correct and the omission of all-important data as to food consumption by animals on test destroys the evidentiary value thereof.

(3) That in view of (2) next above, the fact

stands clearly proven on the record that the 1938-1944 tests showed Red 32 to be harmless at 800 ppm.; that, accordingly, Finding of Fact 2 in the Secretary's final order appealed from, that

"No safe level of administration was found even in test animals for FD&C Red No. 32." (R. 158 at p. 165) was and is wholly incorrect.

(4) That, accordingly, every statement in the Secretary's Petition and brief, as to the alleged toxity of Red 32, should be read as though the Secretary had said, instead, that "Red 32 is toxic when consumed in amounts in excess of 800 parts of color per million parts of the food colored therewith".

In view of all of the foregoing we now respectfully submit that the decision of the Fifth Circuit Court should be sustained, but the Secretary's Order should be reversed in toto.

NEW LEGISLATION

P. L. 85-929, 85th Congress, 2d. Session. (72 Stat. 1784)

Since the foregoing and later sections of this Brief were written, Congress has enacted the above cited law, which was signed by the President on September 6, 1958.

We have included pertinent parts of this new law (to be cited as "Food Additives Amendment of 1958" to the 1938 FD&C Act) under "Statutes Involved" (p. 22-30 supra), and are placing this new section ahead of the main Argument in our brief, because F&DA have published, in official Press Release HEW-135, September 10, 1958, under the heading "Substances Covered", an assertion that "colors" come within the purview of this new Amendment. If this assertion be correct, and if the law comprehends "coal-tar colors", then it may be that the subject mat-

ter of this litigation has become moot, which question the Court may wish to consider first.

We are not prepared to acquiesce in such assertion by F&DA at this time, pending further study of the voluminous Congressional Hearings had on this matter of food additives, together with Senate and House Reports and the law itself, which studies cannot be completed prior to October 14th, next, when this brief must be filed.

Meantime we would call the Court's attention to certain salient facts re this new legislation which are pertinent to the issue in the instant case.

(1) Sub. Pars. (s) and (t) of Sec. 2 of the new law, amending Sec. 201 of the Act, read as follows:

"(s) The term food additive means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, p a c k i n g, processing, preparing, treating, packaging, transporting or holding food * * *).

(which description undoubtedly comprehends certified coal-tar colors) and continues:

"if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as *having been adequately shown* through scientific procedures (or, *in the case of a substance used in food prior to January* 1, 1958, *through* either scientific procedures or *experience based on common use in food*) *to be safe under the conditions of its intended use*; * * * " (Emphasis supplied).

"(t) The term 'safe', as used in paragraph (s)

of this Section and in Section 409, has reference to the health of man or animal."

Whether or not the Congress intended that coal-tar colors be comprehended by the foregoing definition of a food additive, it must be conceded that coal-tar colors are substances added to food and become a component thereof; that the use or intended use thereof results in its "affecting the characteristics" of the food to which added by enhancing the color thereof; that coal-tar colors are used in packing and processing oranges for market.

However, in view of the flat assertions by F&DA, as hereinbefore recited (p. 39 supra) that the coal-tar colors involved in this litigation are "harmless" in the amounts ordinarily consumed in foods" (not just on oranges) and other statements by both the Secretary and F&DA (pp. 40-41 supra) that coal-tar colors as used in coloring oranges are harmless as and in the amounts so used, it seems quite clear that coal-tar colors are, *also* substances that are:

> "* * * generally recognized, among experts qualified by scientific training and experience to evaluate its safety (or in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use; * * *."

Therefore, while it may finally be held that coal-tar colors are one of the "substances covered" by the new law, insofar as concerns the foregoing definition, and especially so since the Congress specifically defined exemptions therefrom but did not include coal-tar colors as an exempted substance, there remains a question as to whether the same are not exempted

from the provisions of the new law by the last above quoted language.

Moreover, the new law does not so much as refer to Sec. 402 (c), which prohibits the use in food of any coal-tar color other than one certified under the provisions of Sec. 406, (in its entirety) nor does the new law mention Section 406 (b) under which coal-tar colors are certified for use, and makes only a technical amendment to Sec. 406 (a) which requires tolerances for deleterious substances in food. Therefore, in view of F&DA's long and continued animosity toward the artificial coloring of oranges, (R. 57, 125-130) we must expect that F&DA will attempt to contend that the Congress did not intend to affect those provisions and that the word "harmless" in 406 (b) must still be construed in its most absolute sense, and that tolerance may not be established for coal-tar colors used for coloring oranges.

If such be F&DA's contention, then we respectfully invite the Court's consideration of these points:

(1) The Congress, in enacting par. (s) of Sec. 201 of the Act as thus amended, discarded the word "harmless" and substituted the words "safe under the conditions of its intended use", when writing a definition of "food additives" that, in its first clause, above quoted, undoubtedly comprehended coal-tar colors and which, likewise, comprehended every other additive that can be added to foods (except poisonous spray resiues, which were already covered by Sec. 408 of the Act).

The substituted language expresses the construction placed upon the word "harmless" by F&DA from 1907 until at least October 13, 1952 (pp. 14 supra); R. 57) which construction F&DA is still applying in the case of all coal-tar colors save those used, or

which could be used, for coloring oranges. F&DA continues to certify all of those other colors, without any question, as "harmless and suitable for use in foods" although none thereof are "harmless" in the absolute sense of that word.

(2) F&DA authored the yardstick of "safe under the conditions of intended use", as applicable to *all* food addities, in H. R. 6747.(1)

(3) In the Secretary's brief (fn. 6, p. 12) it is stated that the Department endorsed "in principle", the provisions of H. R. 8945, 85th Congress. Sec. 5 of that bill reads:

> "(b) *The Secretary shall promulgate regulations providing for the separate listing of color additives* which are suitable for use in food and *which are harmless under the conditions of use specified in such listing.* Such regulations may provide for maximum concentrations for the use of color additive in or on any food, as necessary to protect the public health, and may provide for different maximum concentations of the same color additive in or on different foods, dependent upon the relative importance of each color additive to the several foods in which it is used and the relative significance of those several foods in the human diet. Such regulations also shall provide for the certification of batches of listed color additives, with or without diluents, and for the exemption from certification of color additives the certification of which is not

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(1) It is stated at p. 43, *"Hearings Before A Sub-Committee Of The Committee on Interstate And Foreign Commerce, House Representatives, 85th Congress, *** With Respect To Chemical Additives in Food"* held in July and August, 1957, and April 1958, that F&DA wrote H. R. 6747, which was introduced on April 9, 1957, at F&DA's request. As rewritten in the Committee, H. R. 6747 became H. R. 13,254, which became P. L. 85-929. The "yardstick" language appears in Sec. 2, par. (3) of H. R. 6747.

necessary to protect the public health." (Emphasis supplied).

(4) Insofar as concerns the fixing of tolerances, the provisions of H. R. 6747, Secs. 409 (a), (b) and (c) (1) (A) and (B), as written by F&DA (pp. 4-6 of "Hearing" cited) are substantially identical with the same numbered provisions as the same appear in P. L. 85-929. These sections empower the Secretary to fix tolerances for every conceivable substance that can be added to any and every conceivable article of food, many of which additives are more toxic than coal-tar colors, which latter are admitted by the Secretary and F&DA to be "harmless in the amounts ordinarily consumed in foods". (See pp. 39-40 supra.) Moreover, similar tolerances for coal-tar colors are provided for in the above quoted Sec. 5 (b) of H. R. 8945, which the Secretary endorses "in principle", in fn. 6, p. 12 of his brief.

The "recommendations" as to amendments to H.R. 8945 suggested by the Department on June 27, 1958, are, principally:

(a) That F&DA be empowered (by H.R. 8945) to require retesting of every certifiable coal-tar color, although the toxicity of each of said colors was exhaustively tested by highly qualified, independent research laboratories, and the data thereon submitted to F&DA with application for certification, pursuant to Sec. 135.14, F&DA Coal-Tar Color Regulations (21 C.F.R. 135, part 9) (App. 17-18) the same being thereafter reviewed and further tests made by F&DA and the same found by F&DA to be "harmless and suitable for use in foods", before the colors were admitted to certification and further notwithstanding the fact that the colors are admitted by the Secretary and F&DA to be "harm-

less in the amounts ordinarily consumed in food". (pp. 39-41 supra).

(b) That the Secretary be empowered to reject any application for the certification of any coal-tar color if the same did not have a "functional value" satisfactory to the Secretary, which would, of course, in effect, repeal Congressional approval of the use of coal-tar colors for coloring oranges as found in the first proviso amendment to Sec. 402 (c) of the Act as enacted, and the mandatory "the Secretary *shall* certify" in 406 (b), and enable the Secretary to deny certification to colors indispensable to the coloring of oranges, contrary to known intent of the Congress to insure that this not be done, as shown by the legislative history of the Act. (p. 68-76 infra).

Before the Congress (see "Hearings", fn. 1, p. 46 hereof) F&DA strongly contended for both such powers, i.e., (1) to require "functional value" as to every "food additive", as proposed by F&DA in item (ii) of Sec. 409 (b) (2) (B) and Sec. 409 (c) (3) of H.R. 6747, and (2) to compel retesting of food additives already pretested or proven by long experience to be safe for use in foods.

The Congress rejected both of said contentions by F&DA, and, instead, enacted the parenthetical matter in the last clause of par. (s) of Sec. 201 of the Act as thus amended and, in its rewrite of HR 6747 as H.R. 13254 (P.L. 85-929) deleted every reference to functional value.

This attitude of the Congress was well known to the Department when its recommendations as to H.R. 8945 were written on June 27, 1958, since a prior Committee bill, H. R. 10404, introduced in the House on January 30, 1958, likewise rejected the Department's

bid for powers to compel retesting of all foods additives and to require a "functional value", subject to the Secretary's discretion, only. There is no reason to assume that the Congress would take a different position as to coal-tar colors which are admittedly harmless under intended conditions of use.

Thus it is apparent (1) that the latest thinking of the Congress, as expressed in P.L. 85-929 was to repudiate all "absolute" standards and to require, instead, that all substances added to foods shall be "safe under the conditions of intended use" and (2) that this particular language was fathered by F&DA, who have further informed this Court that the Department endorses a similar yardstick for gauging permitted toxicity in coal-tar colors, as set forth in H. R. 8945, to wit: "harmless under the conditions of use specified in such listing".

(5) That the Secretary, by his endorsement of HR 8945, which construes the word "harmless" as meaning "harmless under the conditions of use specified in such listing" (p. 46 supra) has abandoned, everywhere save in this litigation, his contention that the word "harmless", as used in Sec. 406 (b) of the Act, requires "zero toxicity"; that the Secretary has thereby returned to that relative construction of the word "harmless" which obtained in the Department from 1907 until at least October 13, 1952 (pp. 14 supra).

That this is the deliberate thinking of the Secretary and F&DA, everywhere save in this litigation, is furtherevidenced by the following quotation from Senate Report No. 2422, 85th Congress, 2d. Session, August 18, 1958, re H. R. 13254, reading (p. 2):

"***Conscious of the fact that any subtance or, for that matter, any particular food known to be good

for the health of human beings can be deleterious to the health of an individual who insists on consuming inordinate amounts of it, *the committee agrees with the Food and Drug Administration that, instead of insisting on proof beyond any possible doubt that no harm will result under any conceivable circumstances from the use of a particular additive — which could of course, occur if an individual decided to eat a pound of salt or drink 4 gallons of pure water in an hour — the test which should determine whether or not a particular additive may be used in a specific percentage of relationship to the volume of the product to which it might be added should be that of reasonable certainty in the minds of competent scientists that the additive is not harmful to man or animal, subject to the procedural safeguards provided in the bill which assure the right to hearing and judicial review.*"

Since both of the Courts below have rejected FD&A's contention that the word "harmless" must be construed in its most absolute sense, and since FD&A have now admitted that the proper yardstick is "safe under the intended condition of use", and since the Congress, by P.L. 85-929, has, in effect, fixed the construction of the word "harmless" as used in Sec. 406 (b) as meaning "safe under the conditions of intended use", we respectfully submit that the foregoing disposes of the Secretary's contention that the word "harmless", in Sec. 406 (b), should be construed in its most absolute sense as requiring "zero toxicity" as a condition precedent to certifiability of coal-tar colors.

It is further respectfully submitted that the latest thinking of the Congress on the subject of tolerances, as exemplified by enactment of P.L. 85-929, empower-

ing the Secretary to establish tolerances for every conceivable substance that might be added to any conceivable item of food, likewise rejects the contention of the Secretary, as found in his Finding of Fact 10 of Final Order appealed from (R. 164) and as contended for herein (Petition pp. 13-14; Br. pp. 26-27) that colors are used in so many foods that establishment of proper tolerances therefor is impossible.

The fact that F&DA authored those unlimited tolerance provisions in H.R. (pp. 46) supra) enacted without substantial change in P.L. 85-929, makes it quite clear that the Fifth Circuit Court of Appeals was eminently correct when it found and held R. 182 - 183):

> "The Secretary, in his order, has stated that 'the Department has no means of controlling the amount of colors used in a variety of foods, drugs and cosmetics'. It is not apaparent that this is a problem with respect to other toxic substances which are added to food under tolerances fixed by the Secretary and nothing is shown to indicate that it would be a problem in dealing with a coal-tar color."

We respectfully invite the attention of the Court to the fact that the fixing of tolerances for poisonous or deleterious substances in foods is not mandatorily required by Sec. 406 (a) of the Act unless such tolerances are necessary to the protection of the public health; that in view of the legislative and contemporaneous history of the Act (pp. 76 - 83 infra) it is clear that the word "harmless" in Sec. 406 (b) was construed by F&DA in a relative sense from 1907 until 1953, the colors being used in such minute amounts as to be, in fact, "harmless under the conditions of intended used"; that, accordingly, F&DA has never

prescribed tolerances limiting the amounts of coal-tar colors used in foods, although tolerances were fixed for poisonous substances found in the colors; that this is the only logical — and lawful — explanation of the fact that F&DA is still certifying, r e g u l a r l y, batches of all coal-tar colors used in all foods (save those colors used for coloring orange) without fixing any tolerance for such use.

We respectfully submit that F&DA's ruling as to coloring oranges, only, that those colors are toxic substances, requiring tolerances which cannot be fixed under existing law, constitutes a discriminatory abuse of the powers vested in the Secretary by the 1938 Act.

As stated in the beginning of this Section, F&DA asserts that the new P. L. 85-929 c o m p r e h e n d s "colors" as being food additives.

In view of the record of F&DA's discriminatory acts re colors necessary for coloring oanges, we must expect that, whether or not coal-tar colors are comprehended by the new law, F&DA will, nevertheless, continue its efforts to prevent the use of coal-tar colors for the coloring of oranges.

We, therefore, respectfully pray that, whether or not this Honorable Court should find that coal-tar colors are comprehended within the four corners of new P.L. 85-929, the Court will now resolve each and every the issues in the instant case to the end that the citrus industry of Florida may go its way in peace, without further recurrence of unjustified attacks by F&DA upon its proper and legitimate marketing practices, which attacks have kept the Florida and Texas citrus industry, since 1953, in a state of turmoil and confusion, unable to make proper plans for the guidance of that fast growing industry. Also that industry has been put to heavy and unnecessary expense by

such improper reversal of construction of the word "harmless" by F&DA, including one item of $170,000.00 for research to support application for certification of a new color, although the old color, FD&C Red No. 32, is admittedly "harmless" when used in the amounts ordinarily consumed in food, and for expenses of litigation, including hearings which should never have been called, since the same served only the prodetermined purpose of unholding F&DA's new (1953) construction of the word "harmless", which F&DA now abandons, as to all food additives and colors save coal-tar colors necessary for coloring oranges.

QUESTIONS PRESENTED

I.

DOES THE SECRETARY OF THE DEPARTMENT OF HEALTH, EDUCATION AND WELFARE HAVE AUTHORITY UNDER THE FOOD, DRUG AND COSMETICS ACT OF 1938 TO CERTIFY COAL TAR COLORS FOR LIMITED PURPOSES AND ESTABLISH TOLERANCES FOR THE USE OF SUCH COLORS FOR SUCH PURPOSE?

II.

IS FD&C RED NO. 32 HARMLESS AND SUITABLE FOR COLORING ORANGES UNDER THE LAW AND THE FACTS IN THIS CAUSE?

ARGUMENT

PRELIMINARY STATEMENT

We will present our argument on both questions presented under the following subheads:

(a) The issues in this case.

(b) The language of the Act.

(c) The legislative history of the Act.

(d) Contemporaneous administrative construction of the Act.

(e) FD&C Red No. 32 is harmless and suitable for use in coloring oranges under the law and facts in this case.

(f) The Circuit Court of Appeals of the Fifth Circuit correctly decided this cause.

(g) Conclusion.

(a) The Issues In This Case:

The prime issue in this case revolves around the word "harmless" as the same appears in Section 406 (b) of the 1938 Act, to-wit:

> "The Secretary shall promulgate regulations providing for the listing of coal-tar colors which are harmless and suitable for use in foods * * *."

it being the contention of the Secretary that the word "harmless" must be construed in its *absolute* sense, that is, that before a coal-tar color is listed, it must be proven beyond question to be absolutely harmless for all uses and purposes in whatever amount used and under any and all conditions of use, it being our contention that the intent of Congress was that the word "harmless" be construed in its *relative* sense, that is, that a coal-tar color is "harmless" within contemplation of the Act if it is harmless for the purpose for which it is used and in the amounts used for such purpose.

Another issue in this case revolves around the language of Section 406 (a) and (b) and the language of Section 402 (c), it being the contention of the Secretary that he does not have the authority to list coal-tar colors for limited or particular purposes nor for the coloring of specific foods, nor to establish tolerances governing the amount of such colors to be used

for such purposes and foods, and it being our contention that the Secretary not only has such power but has in fact exercised such power and authority from the time the 1938 Act was passed until the present time.

Another issue is of course whether FD&C Red 32 is "harmless" within the contemplation of the statute for use in coloring oranges under the law and the facts in this case, it being the contention of the Secretary that since Red 32, when consumed in massive doses, is capable of producing adverse effects, it is not "harmless" and it being our contention that the evidence is conclusive; and that it is admitted, that Red 32 is completely harmless for use in coloring oranges.

(b) The Language Of The Act

Section 406 (b) of the Act of 1938 provides:

> "The Secretary shall promulgate regulations providing for the listing of coal-tar colors which are harmless and suitable for use in food and for the certification of batches of such colors, with or without harmless diluents."

The first contention that we make under the language of the above sub-section is that the duty imposed upon the Secretary is a *mandatory duty*, that is, he "* * * *shall* promulgate regulations providing for listing coal tar colors * * *"

Thus we contend that if a coal tar color is "harmless and suitable for use in food" then it is the mandatory duty of the Secretary to promulgate regulations providing for its listing and certification.

We have stated that one of the issues in this case is whether or not the word "harmless" as used in the act is to be construed in its *absolute* sense or in its *relative* sense.

In another section of this brief we will discuss fully the previous administrative interpretation of the act but we think it pertinent now to cite the testimony of Doctor Herbert O. Calvery, former Chief of the Division of Pharmacology, when testifying, in 1939, re certification of coal-tar colors (R. 95):

"Q Are there in your opinion any coal tar colors that are harmless and suitable for use in all kinds and classes of foods, drugs and cometic?

"A. No, in my opinion there are no coal tar colors that are harmless and suitable for use in all kinds and classes of foods, drugs and cosmetics * * *".

and again Dr. Calvery:

"Q. What do you mean by the terms that you have used, harmless and suitable for use? The use to which the color is to be subjected?

"A. Yes, by harmless and suitable for use for purposes indicated, we mean that in the concentrations that these substances are used for coloring purposes, it is our opinion that no harm can come from them to the user when used in the concentration for which they are designed and for the purposes for which they are designed * * *."

It is too fundamental to require citations of authority that words in a statute are to be given the meaning of those words as the same are commonly used and understood in the profession or industry or science to which the statute relates.

In the testimony of Dr. Calvery, we find the meaning of the words "harmless and suitable" as they are used and understood in the scientific world when applied to coal-tar colors for coloring foods.

Thus, in substance, we find that in the field of science it is generally conceded that no coal-tar color

is harmless and suitable for all purposes, that is, harmless under all conditions and circumstances or, in other words, harmless in the absolute sense—but we also find that such colors, although not harmless in the absolute sense of the word, are "harmless and suitable" when used in proper concentrations and for purposes for which they are designed. In other words, they are "harmless" in the relative sense of the word.

In the case of *U. S. vs. Lexington Mill and Elevator Co.* 232 U. S. 399; 58 L. Ed. 658, this Court had before it a statute known as the 1906 Food and Drug Act (34 Stat at L. 768, Chap. 3915, U. S. Comp. Stat. Supp. 1911, P. 1354) which declared that an article was adulterated if it contained "* * * any added poisonous or other added deleterious ingredient which may render such article injurious to health"

The defendant was alleged to have violated the statute by using a "bleaching process" employing an alleged decoloring agent which left in flour a minute amount of a poisonous and deleterious substance and it was the contention of the Secretary, then as now, that if a substance was harmful when consumed in large amounts it might not be used in foods, even when used in such minute amounts as to pose no possibility of danger to the public health. The litigation involved the validity and construction of F&DA Regulation 12 which read: "Only *harmless* colors may be used in food." (Emphasis supplied).

After discussing the purpose of the statute, (to protect the public health) and the fact that the article (flour) which was alleged to be adulterated, was used by the old and the young, the strong and the weak, the well and the sick, and would be used in many ways, in bread, cake, gravy and broth, this Court held, in effect, that even though the added ingredient was a

poisonous and deleterious substance when used in large amounts, yet such fact did not bring the flour under the condemnation of the Statute and stated the proper interpretation to be:

> "If it cannot by any possibility, when the facts are reasonably considered, injure the health of any consumer, such flour, though have a small addition of poisonous or deleterious ingredients, may not be condemned under the act."

Thus we find that, in a case involving the addition to foods of a substance that was "harmless in the amounts ordinarily consumed in foods, but * * * not harmless when fed in large amounts", and involving, also, the construction of the word "harmless" as used in F&DA Regulation 12, this Court held that the word "injurious", when used in a statute relating to food, is to be construed in its relative sense and not in an absolute sense.

Both Courts below followed that decision of this Court and both Courts below rejected the contention of the Secretary that the word "harmless" must be construed in its most absolute sense.

In the Second Circuit Court case (236 Fed. 2d 866) the Court said:

> "Petitioners argue that the 1938 amendment, insofar as these sections are concerned, amounts to nothing more than legislative recognition of existing practice and procedure; that the word 'harmless' must be equated to 'added poisonous or other added deleterious ingredient which may render such article injurious to healts,' and that these words must be given the meaning assigned to them in *Wood Mfg. Co. v. United States*, 286 Fed. 84 (7th Cir. 1923). The *Wood* case adopted a standard of

relativity and held that an infinitesimal quantity of arsenic in a coal-tar color was not a poisonous or deleterious substance, injurious to health, as ordinarily used, and that the government was required to prove that the substance was in fact injurious as used Respondent, on the other hand, urges that the use of a different word—'harmless'—instead of the more familiar statutory language is evidence of Congressional intent to provide an absolute standard. *We are unable to agree with either of these interpretations.*" (Emphasis supplied).

and cited as controlling that paragraph of this Court's decision in *U. S. vs. Lexington Mill & Elevator Co.*, (232 U. S. 399) which concludes with the above quotation therefrom.

In the Fifth Circuit Court decision (246 Fed. 2d 850, R. p. 80) the Court cited the language of the above quotation as authority for rejecting the Secretary's contention that the word harmless must be construed in its most absolute sense.

We, therefore, contend that the word "harmless" is to be construed in its relative sense and that, when applied to coal-tar colors, the word means "harmless when used in proper concentrations and for purposes for which they are designed".

Let us now see if the color Red 32, as used for the purpose for which we contend it is proper to use it, to-wit; coloring oranges, could under "any possibility, when the facts are reasonably considered, be injurious to the health of any consumer" of the oranges.

We have in previous sections of this Brief demonstrated that the tests relied upon to decertify Red 32 were unconclusive in many ways but on one point they were definitely conclusive—and that point is

decisive of this case—that is—Red 32 is harmless when used for coloring oranges.

We see no need to belabor a point as freely and fully admitted as the above fact.

The following admissions and statements establish that Red 32 is harmless when ued to color orange:

On February 7, 1955, Commissioner George P. Larrick addressed a letter to United States Senator George Smathers of Florida, over the seal of the Department, which letter contained the following statement (R. 135-136):

> "The proposal to remove these coal-tar colors including FD&C Red No. 32, from the list of colors eligible for certification for use in foods results from the requirement of the pure food law that only colors that are harmless are eligible for certification. Recent investigations show that these colors, when fed in *substantial* amounts, show evidence of toxicity. *There is, however, no evidence that, in the amounts used, and in the manner of use, in the coloring of citrus fruit, the product so colored is not safe* for human consumption." (Emphasis supplied).

On November 16, 1955, in an official Press Release of the Department, announcing the final Order appealed from, by which Red 32 and two other colors were removed from the list of certifiable colors, Commissioner Larrick made the flat statement that those three colors are harmless not only for use in coloring oranges, but are harmless for use in coloring *all* foods, in these words (Press Release HEW C-81) (App. 22):

> *"FDA Commissioner George P. Larrick said the three colors involved are harmless in the amounts ordinarily consumed in foods; but* recent scientific investigations shows they are *not harm-*

less when fed in large amounts. (Emphasis supplied).

"The colors involved are FD&C Orange No. 1, FD&C Orange No. 2, and FD&C Red No. 32. Orange No. 1 has been widely used in candy, cakes, cookies, carbonated beverages, desserts and meat products, particularly hot dogs. Orange No. 2 and Red No. 32 are the dyes which have been used in coloring the outer skin of oranges."

In "Report of Hearing on H. R. 7732 etc., on February 10, 1956" (p. 8 supra) in his testimony before the House Committee, Commissioner Larrick made the following statment (p. 18 of Report):

"Considering all of the information so far available—*and bearing in mind particularly the minute amount of this dye likely to enter the human diet as a result of its use on oranges—we cannot say that its continued use on oranges* not intended for procesing *would pose a hazard to the public health.*" (Emphasis supplied).

In that same Report, in the letter of Secretary Folsom, dated February 13, 1956 (which letter was dated three days after the hearing) we find the following statement (pp. 2-3 of Report):

"While the scientific evidence so far available does not establish what the lowest safe dosage would be to test animals, *neither does it establish a likelihood of injury to man from use of this color on the exterior of oranges at the level of use involved.* * * *" (Emphasis supplied).

We therefore submit that, using nothing but the language of the Act, as construed by the Courts below, we have established that Red 32 is "harmless"

for coloring oranges within the contemplation of the 1938 Act.

The Court of Appeals of the Fifth Circuit specifically held:

> "The words 'harm', 'harmful', and harmless' are terms of relation." (R-179).

We submit the Court was eminently correct.

There is other significant language of the 1938 Act which further supports our contention, which is that in the entire Act citrus fruit is the only food mentioned by name. Section 402 (c), as originally enacted, read as follows:

> "(c) If it bears or contains a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by Section 406: *Provided, That this paragraph shall not apply to citrus fruit bearing or containing a coal-tar color if application for listing of such color has been made under this Act and such application has not been acted on by the Secretary, if such color was commonly used prior to the enactment of this Act for the purpose of coloring citrus fruit.*" (Emphasis supplied).

We submit that the above language evidences a very thorough knowledge on the part of Congress of the importance of color to the citrus industry and an intent that the color in use for coloring oranges (Red 32) be not interfered with.

We come now to the second issue in this case, that is, whether or not the Secretary has the authority under the Act of 1938 to certify a coal-tar color for a specific purpose and establish the amount of such color that may be used for such purpose.

We respectfully direct the Court's attention to the

fact that there is not a single word in the entire Act that restricts the authority of the Secretary in this regard.

The Court of Appeals of the Fifth Circuit specifically noted this fact and said:

> "In the order of the Secretary it is stated that there is no 'Authority to limit a color, once certified, to a single food—for example, FD&C Red No. 32 for use in color-added oranges.' *Although there may be no express statutory provisions authorizing the limiting of the use of a color to a single food, it is not* prohibited." (Emphasis supplied) (R. 183).

When we consider that Congress singled out one particular item of food, citrus fruit, and made specific provisions for continued use of color therefor, we cannot but be constrained to contend that the Secretary's interpretation is manifestly arbitrary and capricious. We refrain from elaborating upon the somewhat unusual spectacle of an executive officer contending for a construction of a statute that limits his authority.

Under that unrestricted authority of Section 406 of the Act, the Secretary, through F&DA, has, in Coal Tar Color Regulations (21 CFR 135; 1940) Sec. 135.02, fixed tolerances for such poisons as arsenic and lead in coal-tar food colors. Obviously, if the Secretary has authority to fix tolerances for deadly poisons such as arsenic and lead when found in coal-tar colors, then the Secretary has like authority to fix tolerances for the coal-tar colors which contain those deadly poisons, when such colors are used in food.

The Secretary was correct in fixing those tolerances for poisons in coal-tar colors. It follows, as of course, that those colors, still containing those poisons,

are not "harmless" in that absolute sense of the word contended for by the Secretary, hence the Secretary is mandatorily required to fix tolerances for those colors when used in food, unless he is prepared to return to that construction of the word "harmless", in its relative sense, which prevailed from 1907 to October 13, 1952, and which still obtains as to all colors except those used for coloring oranges, as to which latter colors, only, he asserts (1) that the colors are not harmless and (2) that he has no power to fix tolerances. All other certified coal-tar colors have been and continue to be certified, without tolerances, although no more "harmless" than Red 32.

In Sec. 406 (b) Congress mandatorily instructed certification of coal-tar colors that are "harmless and suitable for use in foods"; under Sec. 504, the colors must be "harmless and suitable for use in drugs", and under Sec. 604 the colors must be "harmless and suitable for use in cosmetics. If "harmless" as used in 406 (b) is to be construed in its absolute sense, then "harmless" as used in Secs. 504 and 604 must be similarly construed.

Yet under Sec. 135.03 of that Regulation, F&DA lists 18 colors that are certifiable as "harmless and suitable for use" in food, drugs and cosmetics; under Section 135.04 are listed scores of other coal-tar colors that are certifiable as "harmless and suitable for use" in drugs and cosmetics, while under Section 135.05 there are listed many more coal-tar colors that are certifiable as "harmless and suitable for use" in externally applied drugs and cosmetics, all three classes is being of different degrees of purity.

There are two questions that F&DA has never answered:

(1) If all certified coal-tar colors must be of zero toxicity, hence suitable for use in all three classifications, and if the Secretary has no power to restrict the use of coal-tar colors to specific uses, as he contends, by what authority are these three classes of colors thus restricted to three separate categories of use?

(2) If these colors are not of zero toxicity, why are some still being certified without fixing tolerances therefore?

In a later section of this Brief we will show by the legislative history and the former administrative interpretation of the 1938 Act that it was the intent of Congress that the Secretary should have authority to limit the use of a coal-tar color to a specific use or food and to establish tolerances as to the amount thereof for such use.

We come now to the third issue in this case, that is whether or not the Secretary has the power to establish tolerances limiting the amount of such color that may be used for such puposes as the Secretary may specify.

Again confining our argument in this section of this Brief to the language of the Act, we find that Section 402 (c) provides that a food shall be deemed to be adulterated if it contains a coal-tar color *other than one certified* in accordance with regulations *as provided in Section* 406.

We particularly direct the Court's attention to the fact that the reference is to *Section* 406 in its entirely, not to any sub-sections, or part or portions of such sections, but to the entire Section 406.

The significance of this reference is that *Section* 406 has two sub-sections, (a) and (b).

Sub-section (a) of Section 406 relates to the power and authority of the Secretary to limit the quantity of any poisonous or deleterious substance to be tolerated in any food where such poisonous or deleterious substance is required in the production of such food.

Sub-section (b) of Section 406 provides for certification of coal-tar colors that are harmless and suitable for use in food.

We submit that the language of the aboye Sections of the 1938 Act are susceptible to two constructions, both favorable to our contention that the Secreary has authority to establish tolerances for the use of Red 32 in coloring oranges.

The first construction for which we contend is that the coloring of oranges is an economic necessity and therefore the Secretary should establish tolerances for the use of color in the industry.

It is an established fact (p. 4 supra) that oranges reach theie full maturity as to sweetness, size and acidity before the color of the skin changes to the yellow color that the purchasing public associates with ripeness and maturity and that the orange has passed its peak of perfection before the yellow color of the skin naturally appears and makes the same a marketable commodity, hence the necessity for artificial coloring.

The mere production of a food product is not an end of itself; the purpose of production of food is its ultimate purchase and consumption by the public. Since it is established that coloring of oranges is essential to their marketability and considering the concern of Congress for assuring the coloring and marketing of oranges it can reasonably be contended that

the phrase "required in production" embraces and contemplates that coloring is a part of the production of oranges.

The Court of Appeals of the Fifth Circuit construed the 1938 Act to require the Secretary to determine whether or not coloring of oranges was "required in production" thereof, and if so to establish tolerances for the use of suitable colors for such purpose. (R. 183).

The second construction that may be placed upon the reference in Section 402 (c) to the entire Section 406 is that Congress intended that both sub-sections of Section 406 should be applicable—that is, the Congress vested in the Secretary the power to (1) certify coal-tar colors for coloring food and (2) to establish tolerances for the use thereof in food, when, in the judgement of the Secretary, colors that are harmless under the conditions of intended use might be harmful when consumed in large quantities.

Certainly we know that *Congress showed more concern for the* continued *coloring of citrus fruit than for any other food* product, *when it* specifically *approved* the practice of *coloring citrus fruit and made special provisions for continuance of this practice* and *recognized that coal-tar colors are inherently toxic* by forbidding their use except under strict regulation as to certification and as to amounts to be used. We submit that, against this background of the evident purpose and intent of Congress, the Secretary's contention that Congress had no intent to give him authority to provide colors for use in coloring oranges appears somewhat arbitrary and even faintly ridiculous.

Thus when we consider nothing but the bare language of the 1938 Act it appears that:

1. F&DC No. 32 is "harmless" for coloring oranges within the contemplation of the Act.
2. The Secretary has the authority and is under the duty to certify Red 32 for coloring oranges and establish the amount that may be used for such purpose.

We will next discuss the regulatory and legislative history of the word "harmless" as used in Section 406 (b) of the 1938 Act:

Legislative History Of The Act.

We now respectfully submit that the legislative history of the Act makes it very clear (1) that Congress used the word "harmless" in its relative sense and not in any "absolute" sense as contended by F&DA and (2) that the Congress mandatorily required the Secretary to establish tolerances for coal tar colors under Sec. 406 (a).

Prior to the 1938 Act, there was no specific statutory use of the word "harmless". The various regulations relating to coal-tar food colors were issued by F&DA under the general language of the 1906 Act, which provided that food would be deemed to be adulterated:

> "**if it contains any aded poisonous *or other added deleterious ingredients* which may render such article injurious to health." (F&D Act of 1906; Sec. 7, 34 Stat. 769) (Emphasis supplied.)

However, use of the word "harmless", in the regulation of coal-tar food colors, goes back to the first coal tar color regulations ever issued on such colors under authority of the 1906 F&D Act, being Regulations 12 and 13, Bureau of Chemistry, 1907, which were reissued, in 1927, as Regulation 13, reading:

"(a) Only *harmless* colors and *harmless* preser-

vatives may be used in articles of food." (originally

"(b) A color, preservative, or other substance, Reg. 12).

even though *harmless*, shall not be used in the preparation of any food in a manner whereby damage or inferiority is concealed." (originally Reg. 13). (Emphasis ours).

The same or equivalent language was carried forward in reissues of such regulations and remained in effect (See Dunn. p. 1348) until the 1938 Act was enacted, when the word "harmless" was merely transplanted into the Act, in Subsection 406 (b), reading:

"(b) The Secretary shall promulgate regulations providing for the listing of coal-tar colors which are *harmless* and suitable for use in food and for the certification of batches of such colors, with or without *harmless diluents.*" (Emphasis ours).

The purpose and intent of the Congress in enacting section 406 (b) was stated in clear cut, direct terms. From the first hearing on the bill S-1944 (73rd Congress, 1st Session, 1933, see Dunn, Ap. B. p. 1066) until the final mention of the section in the House Report on Bill S-5 as enacted (75th Congress, 3rd Session, 1938, see Dunn, p. 820) that purpose and intent was emphasized repeatedly, in such words as these:

"This continues in effect a system of certification which has been followed almost from the beginning of the enforcement of the old food and drug law" * * *, (Dunn, p. 820, emphasis ours).

The testimony of Mr. W G. Campbell, Chief of F&DA, before the Senate Committee on Commerce, on December 7, 1933, on this subject, reads (Dunn, pp. 1065-66).

"MR. CAMPBELL: * * * "Paragraph (d) of this act makes it an offense to use a coal-tar other than one from a batch that has been certified by the Secretary in accordance with the regulations as hereinafter provided.

"In section 10, to which we referred, on page 14, you will find, in the record paragraph of that section, line 8, page 15, that the Secretary is authorized to make regulations after notice and hearing, for the *certification of coal-tar colors which he finds to be harmless* for use in food."

"The CHAIRMAN. That is not in the law now?

"Mr. CAMPBELL. That is not in the law now.

The CHAIRMAN. It is there by regulation?

"Mr. CAMPBELL. By regulation we have actually done that. After the existing law became effective the then Bureau of Chemistry, *in recognition of the impurities to be extensively found in a great many coal tar colors and the poisonous character of some of the colors themselves,* issued regulations designed to assure the manufacturers and other purchasers that the colors used by them would be non toxic and free from deleterious ingredients. These regulations established the practice of examining the *purity and safety* of coal-tar (colors) as a method for the protection of the public.

"It is desirable that it be continued. In this language we are asking for legislative confirmation of a practice which has existed since 1907." (Dunn, pp. 1065-66) (Emphasis supplied.)

We now respectfully direct the attention of the Court to the fact that when Mr. Campbell thus testified *the decision of this Court in the Lexington Mill case,* 232 U. S. 399, *had been the law on this point for* 19 *years; that the principles there laid down by the*

Court were an integral part of the "practice" which Mr. Campbell was here asking the Congress to reaffirm by legislative action and continue in effect.

When read in the light of these statements, there is not a word in the legislative history of the Act which supports the contention of F&DA herein that the Congress intended to limit certification of coal-tar food colors to those that were "harmless" in the absolute sense of that word. Until at least October 13, 1952 (R. 57) F&DA were statedly of the same conviction.

Since Orange 1, decertified by the order appealed from, and Yellow OB (FD&C Yellow No. 4) and Yellow AB (FD&C Yellow No. 3) (now sought to be decertified per "Proposed Rule Making" published in Federal Register for May 4th, 1957, p. 3173), are three of the colors certified in those early days, it is apparent that the word "harmless" was always used in its "relative" sense, since certification would have been prohibited if the word "harmless" had been used in its "absolute" sense.

Since five years have elapsed since F&DA made its initial attempt in 1953 to construe the word "harmless" in an "absolute" sense, rather than the "relative" sense theretofore followed, and since 12 coal-tar colors, all containing such poison, are still on the certified list and unchallenged as to their "harmlessness", it follows that F&DA is still construing the word "harmless" in its "relative" sense insofar as those 12 coal-tar colors are concerned.

We now further respectfully submit that, specifically, the last amendments to Sec. 402 (c), 406 (a) and 406 (b), prior to enactment of the Act, make it very clear that each of those amendments were enacted pursuant to a very evident puupose and intent of the Con-

gress to insure the continued used of coal-tar colors for coloring citrus fruit.

The pertinent parts of the bill "Senate 5 — 75th Congress" as it passed the Senate on March 9, 1937, (Dunn, p. 746) read as follows:

Sec. 11 (enacted as section 402) then read:

"Sec. 11. A food shall be deemed to be adulterated:

"(c) If it contains a coal tar color other than one from a batch that has been certified in accordance with regulations as provided by Section 15." (Dunn 782).

Sec. 15 (enacted as Sec. 406) then read:

"Sec. 15 (a) Any contaminating, poisonous, or deleterious substance added to any food, except when such substance is required in the production thereof or cannot be avoided by good manufacturing practice, shall be deemed to be unsafe for purpose of the application of section 11 (a), but when such substance is so required or cannot be so avoided, the Secretary *is authorized* to promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of the public health. * * *

"(b) The Secretary *is hereby authorized* to promulgate regulations for the certification of coal-tar colors which are harmless and suitable for use in foods." (Dunn, p. 785). (Emphasis supplied).

The Bill went to the House Committee on Interstate and Foreign Commerce on March 10, 1937, where it remained until August 20th, 1937, when that Committee presented to the House a revised bill (Dunn, p. 751) arrived at by striking everything in the Bill

as passed by the Senate except the title and enacting clause and inserting a House Committee draft.

We find these amendments in this new House draft of the bill, recommended to the consideration of the House on August 20th, 1937 (Dunn, 752) in the sections here concerned:

"Sec. 402. A food shall be deemed to be adulterated—

"(c) If it *bears or* contains a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by section 406: *Provided, that this paragraph shall not apply to citrus fruit bearing or containing a coal-tar color if application for listing of such color has been made under this act and such application has not been acted on by the Secretary, if such color was commonly used prior to the enactment of this act for the purpose of coloring citrus fruit.*" (Emphasized mater is amendment concerned).

"Sec. 406 (a) Any poisonous or deleterious substance added to any food, except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice shall be deemed to be unsafe for purposes of the application of *clause* (2) *of* section 402 (a); but when such substance is so required or cannot be so avoided, the Secretary *shall* promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health, and any quantity exceeding the limits so fixed shall also be deemed to be unsafe for the purpose of the application *of clause* 2 *of* Sec. 402 (a). *While such a regulation is in effect, limiting the quantity of any such substance in the case of any food, such food shall not, by reason of bearing or containing*

any added amount of such substance, be considered to be adulterated within the meaning of clause (1) *of Sec.* 402 (a) * * *". (Emphasized matter indicates amendment concerned).

"(b) The Secretary *shall* promulgate regulations providing for the listing of coal tar colors that are harmless and suitable for use in food and for the certification of batches of such colors, with or without harmless diluents." (Emphasized matter indicates amendment concerned).

The purpose and intent of the Congress in adding the "proviso" clause to Sec. 402 (c) is crystal clear. The language used is susceptible of but one interpretation — that coal-tar colors were then being used to color citrus fruit, which practice enjoyed Congressional approval; that application for certification of a color so used had been made but had not been acted upon by the Secretary; that to the end that such coloring practice be not stopped or interfered with by the failure or refusal of a Secretary to certify need colors, Congress was granting special authority for the continued use of that color until the application for certification thereof had been acted upon by the Secretary.

When the corollary amendments to Section 406 are considered in the light of the addition of that "proviso" amendment to Section 402 (c), the purpose and intent of the Congress in enactig those amendments is likewise crystal clear.

As admitted by the Secretary's petition (PB. 19, lines 7-9 of designated par. "A", and cited authorities) Congress was fully informed and advised that: "Coal tar colors have always been recognized as having potentialities of danger" Those coal-tar colors were known to contain small amounts of arsenic and lead, together with other deleterious substances pro-

duced by side reactions during manufacture (see F&DA Coal-Tar Color Regulations (Sec. 135.02, 135.-03; app. 9 - 14). Sec. 201 (f) defines "food" as "(1) articles used for food or drink for man or other animals, * * * (3) articles used for components of any such article", under which definition coal-tar colors are, of course, a food.

Coal-tar colors containing such poisonous or deleterious substances were, therefore, clearly within the interdiction of section 402 (a) unless tolerances were prescribed therefor. So long as the statutory power to fix tolerances and certify colors was permissive or discretionary with the Secretary, the use of coal-tar colors for the coloring of citrus fuits could be stopped or interfered with by the failure or refusal of a Secretary to establish necessary tolerances therefor, or to certify needed colors.

The Congress, therefore, pursuant to its purpose and intent, so clearly evidenced by the amendment to section 402 (c), to insure the continued use of coal-tar colors for coloring citrus fruit, amended Section 406 (a) by changing the permissive "the Secretary is authorized" to the mandatory "the Secretary *shall*" and by spelling out the exemption accorded to foods containing such tolerated amounts of deleterious substances.

Pursuant to the same intent, Congress also amended Section 406 (b) by again changing the permissive "the Secretary is hereby authorized" to the mandatory "the Secretary *shall*".

That the amendments to Sections 402 (c) and 406 (b) are of the same origin and purpose, is further evidenced by the fact that the proviso amendment to section 402 (c) and section 406 (b) both refer to the

"listing" of certifiable colors, "listing" being a word never before used in the proposed legislation.

Although these amendments were of decided importance, especially to F&DA, Dunn reports no reference whatever to those amendments in any Report or debate on the Act. The majority Report to the House (Dunn, p. 819-820) and the Minority Report (Dunn, 834) are silent thereon, and there is no mention thereof in the prolonged debate in the House (Dunn, 840-963), nor, the Senate having refused to agree to another House amendment, in the Conference Report and statement in the House (Dunn, 970-996). There was no debate in the Senate on either the House rewrite or the conference report. (See, here, R. 130).

Since all of the coal-tar colors certified prior to enactment of the 1938 Act (including Orange No. 1 and Orange No. 2) were recertified in 1939, it is very clear that the Department did not ask, nor did Congress enact, any new requirement of zero toxicity; that, as Mr. Campbell and the Senate Report stated, Congress was asked to give — and Congress gave — legislative sanction to the prior Department practices re certification of colors — that and no more.

In the light of the foregoing, we will now discuss:

(c) The Legislative History of the Act, and

(d) Contemporaneous Administrative Construction of the Act.

We will consider these two matters together for the sake of brevity and because the legislative history of the 1938 Act clearly evidences the intent of Congress as to the issues of this case and because that intent was so well known to the officials charged with the responsibility of administering the Act that there was no variance between the intent of the Congress and the adminstration of ihe Act by such officials.

It is our basic contention that, on each and every issue in this case, F&DA has completely changed its position, reversed its former contentions, and departed from its previous interpretations of the law and that such changes, reversals and departures have resulted in defeating the clear intent of the Congress.

Let us first direct our attention to the word "harmless" as the same appears in Section 406 (b).

Almost contemporaneously with the passage of the 1938 Act Dr. Herbert O. Calvery, F&DA's Chief of the Division of Pharmacology, testified re basis for certification of coal-tar colors, as follows (U. S. D. A. FD&C No. 4, February 7, 1939). (R. 95-6):

"Q. What do you mean by the terms, that you have used, 'harmless and suitable for use'? The use to which the color is to be subjected?

"A. Yes, by 'harmless and suitable for use' for purposes indicated, we mean that in the concentrations that these substances are used for coloring purposes, it is our opinion that no harm can come from them to the user when used in the concentrations for which they are designed and for the purposes for which they are designed.

"Q. In considering the amount used, does the tinctorial properties of these coal-tar colors have some bearing on the amount used?

"A. Yes, the tinctorial properties of the coal-tar colors is such that when they are used in foods, drugs and cosmetics they are used in relatively small percentages, and one takes that into consideration when one speaks of the toxicity of these substances assumed as harmless and suitable for use in drugs and cosmetics.

"Q. Dr. Calvery, how do you arrive at percentage

of color which should be allowed as harmless and suitable for use in foods, drugs and cosmetics?

"A. We arrived at the conclusion that we have concerning the use of these from our conferences with the cosmetics, food and drug manufacturers, and after learning from them what the percentages are, which in most cases are a fraction of a per cent, we based our reasoning on that premise. *The colors are not certified for use as colors to be consumed as colors. They are certified—at least we are permitting the listing of these for certification—on the basis of the fact that they will be used as we have been told they are being used at the present time, that is, in small percentages.*

"Q. Now, have you reached an opinion as to the maximum percentages of coal tar colors which would be allowable respectively in foods, drugs and cosmetics, in view of the tolerances for impurities which have been established in these present regulations.

"A. No, we haven't reached a definite conclusion as to what is the maximum that may be permitted. *It is our understanding* as I pointed out before *that these colors are used in relatively small amounts, in most cases only a fraction of one per cent in the finished product.*

"— If manufacturing processes and the use of these colors should change to such an extent that more than these amounts should be used, on or which we have actually taken into consideration in considering the toxicity of these colors, *if that should change to an extent whereby larger amounts would be used,* I think there would be no question but that *we would have to* take that into considera-

tion in order of time and *consider amendments to the present regulation.*" (Emphasis supplied).

Thus it appears that the contemporaneous interpretation of the law was that "harmless" was used in the 1938 Act in its relative sense; that coal-tar colors could be certified for specific purposes and that when necessary the Secretary had authority to regulate the amount to be used, and that the statute not only authorized but directed and required the fixing of tolerances for color-tar colors, when necessary for the protection of the public health.

Let us resort to a comparison of *present* interpretation of the Secretary and of the past interpretations:

Finding of Fact 10 of the Order of the Secretary is as follows (R. 158):

"10. There was no evidence on which findings could be made concerning how much of the three colors is likely to be ingested by man from his food, drugs and cosmetics. Some interested persons, taking their own products, attempted to show that the amounts ingested would be small to the point of insignificance. But those contentions leave aside the occurence of the colors in the products of others, as well as the fact that upon certification of a color the Department has no means of controlling the amounts of colors used in a variety of foods, drugs and cosmetics. Nor is there authority to limit a color, once certified, to a single food—for example, FD&C Red No. 32 for use in color-added oranges." (R. 164).

The comparison of the *present* interpretation of the Secretary with the testimony of Dr. Calvery above quoted is rather startling, but let us look, for further contrast, to the testimony of Hon. Walter G. Campbell,

Chief of Food and Drug Adminisration and principal legislative spokesman for the Department, from 1933 through to adoption of the Act in 1938 and, thereafter, the officer charged with initial administration of the Act. Mr. Campbell testified before the Senate Committee on Labor and Commerce on December 30, 1933, ré Senate Bill 1944, as to the necessity that FD&A be empowered to establish tolerances—the section under discussion being almost identical with present Section 406 (Dunn, pp. 1056-57):

*"This is an extremely important, in fact, one of the most important provisions of this bill. It may be impossible to preclude absolutely poisonous ingredients from food. Some of the deleterious ingredients with which we have to deal are to be found universally. But it is important that they not only be kept to such a low limit in each article of food in which they may be found that that article of food itself may not be dangerous to health, but important, furthermore, that the total intake of poisons by the consumer of foods from all sources be restricted to an amount which will not be dangerous to health. * * *"*

"You know the extent to which this matter has been agitated; fruit and vegetable growers have followed the instructions issued them by official agencies for the use of insecticides. It became the obligation of the same agencies then to advise the growers about methods by which this spray residue could be removed. *Methods more or less satisfactory have been devised, and in the majority of cases, particularly the fruit products, the amount of residue encountered now is below the tolerance which has been determined as safe for consumption. But, Mr. Chairman,* and this is another important argu-

ment for this particular paragraph, *under the terms of the present law we are able to consider only a single commodity.If that single article of food does not contain poison in excess of the tolerance that has been determined as safe for consumption, it is not in violation of the present law. But suppose that article contains just a little less than the safe tolerance. Multiply that by the number of articles of food also containing traces of added poisons which constitute our daily diet, and you can get some conception of what the general intake of poisonous substances would be.*" (Emphasis supplied).

Thus when F&DA was seeking, in 1933, to enlarge its powers, it solicited from the Congress and was granted power to prescribe tolerances for *every* possibly deleterious substance that could by any chance find its way into *any* article of food in the Nation's dietary, and premised its solicitation upon the urgent necessity for establishing tolerances that would comprehend "the total intake of poisons by the consumer of foods from all sources".

But when F&DA wishes to evade the mandatory directive of the Congress to establish such tolerances for coal-tar colors used for coloring oranges, which colors are admittedly harmless as used, the task becomes impossible, beyond the powers of F&DA, because the color is used in so many different foods.

The Fifth Circuit Court cut through such evasions with the following comment (R. 168 at p. 182):

"The Secretary, in his order, has stated that 'the Department has no means of controlling the amounts of colors used in a variety of foods, drugs and cosmetics,' It is not apparent that this is a problem with respect to other toxic substances which are added to foods under tolerances fixed

by the Secretary and nothing is shown to indicate that it would be a problem in dealing with a coal-tar color.' * * *."

But we do not need to rely only upon the testimony of Mr. Campbell and Dr. Calvery to show the contemporaneous interpretation of the Act. The official publications of F&DA bear witness to the changes, reversals and departures of the Secretary from previous interpretations.

In the official publication **"Coal-Tar Color Regulations" (21 CFR 135)** promulgated and published August 27, 1940, and still in effect, we find that tolerances were established and coal-tar colors restricted to specific purposes as follows:

(1) Sec. 135.02 prescribes tolerances for arsenic, lead and other heavy metals, in *all certified coal-tar colors.* (App. 9-10).

(2) Sec. 135.03, under "Specifications" for each coal-tar color certified for use in foods, drugs and cosmetics, establishes tolerances for other deleterious substances found therein. (App. 11-13).

(3) Sec. 136.03 also states general authority for certification of all FD&C colors (app. 10-11) but makes certification subject to the restrictions of sub-par. (c) thereof, which reads:

> (c) No lake listed in sub-section (a) shall be certified for any use in food except *external application to shell eggs.* (Emphasis supplied).

Thus we see that F&DA in 1940 definitely restricted the use of certain colors to external application to shell eggs, but now contend that there is no authority to restrict the use of a coal-tar color to the one purpose of external application to the skins of oranges, as heretofore mentioned (R. 158 at 164).

In the same official publication we find in Section 135.11 (4) (page 41) the provisions for labeling coal-tar colors and specific provisions being made that the label show *the specific food for which certification of the color is sought.* (App. 17).

Again, in Sec. 135.06 (3) under Mixtures Which May Be Certified, it is clearly contemplated that mixtures shall be certified for use only in specified food.

Thus we see that the Secretary has prescribed tolerances for the poisonous ingredients of coal-tar colors and has limited colors containing certain ingredients to a particular purpose and actually made provision in his regulations for labeling coal-tar colors for use in a specified food.

We submit therefore that the evidence is conclusive that, contemporaneously with the passage of the Act, the interpretation of the Act by the Administrative agency was that tolerances could be fixed for use of coal-tar colors and that a coal-tar color could be restricted to a particular purpose and for a specific food.

(e) F&DC Red No. 32 is harmless and suitable for use in coloring oranges under the law and facts in this case.

We have heretofore analyzed the tests upon which the Secretary based his order and will not burden the Court with repeating that portion that demonstrates that the tests are inconclusive and indecisive.

One further reason why we need not further argue the tests is of course that we need not argue that which is admitted — and the correctness of our contentions on the only factual issue in this case is fully admitted — that is, that there is no proof whatever that F&DC Red No. 32 is harmful in any way when used for the purpose of coloring oranges.

These admissions have been quoted before but we repeat them for convenience:

The following admissions and statements establish that Red 32 is harmless when used to color oranges.

On February 7, 1955, Commissioner George P. Larrick of F&DA addressed a letter to United States Senator George Smathers of Florida, over the seal of the Department, which letter contained the following statement (R. 135-136):

> "The proposal to remove these coal-tar colors, including FD&C Red No. 32, from the list of colors eligible for certification for use in foods results from the requirement of the pure food law that only colors that are harmless are eligible for certification. Recent investigations show that these colors, when fed in *substantial* amounts, show evidence of toxicity. *There is, however, no evidence that, in the amounts used, and in the manner of use, in the coloring of citrus fruit, the product so colored is not safe* for human consumption." (Emphasis supplied).

In the "Report of Hearing on H. R. 7732" etc., on February 10, 1956 (p. 8 supra) in his testimony before the House Committee, Commissioner George P. Larrick made the following statement (p. 18 of Report):

> "Considering all of the information so far available - *and bearing in mind particularly the minute amount of this dye likely to enter the human diet as a result of its use on oranges - we cannot say that its continued use on oranges* not intended for processing *would pose a hazard to the public health.*" (Emphasis supplied.).

In that same Report in the letter of Secretary Folsom, dated February 13, 1956, (which letter was dat-

ed three days after the hearing) we find the following statement (pp. 2-3 of Report):

"While the scientific evidence so far available does not establish that the lowest safe dosage would be to test animals, *neither does it establish a likelihood of injury to man from use of this color on the exterior of oranges at the level of use involved.* ***" (Emphasis supplied).

We submit therefore that it conclusively appears that F&DC Red No. 32 is harmless and suitable for use in coloring oranges.

(f) The Court of Appeals of the Fifth Circuit correctly decided the issues in this case.

There are but two major issues in this case, one of law and one of fact.

The issue of law is one of construction and interpretation and revolves around the intent of Congress as expressed in the word "harmless."

The issue of fact is whether or not F&DC Red No. 32 is "harmless" within the meaning of that word as used in the 1938 Act when such color is used for coloring oranges.

We have cited the opinion of this Court in the Lexington Mill case (pp. 57-58 supra) which we submit is conclusive on the issue of law and the Court of Appeals of the Fifth Circuit followed that case in holding that the word "harmless" was to be construed in a relative sense.

In deciding this point the Fifth Circuit Court said:

"The words 'harm', 'harmful', and 'harmless' are terms of relation. In this sense they r e s e m b l e 'wrong' and 'wrongful'. Red 32 is harmless, i.e. not harmful, to all persons under the protection of the

Act while it remains in the vat or the vial. An injury must occur before harm results. The color Red 32 becomes harmful, i.e. not harmless, when it is consumed, and then only if consumed in such quantity that injury or harm might result. If there can be a use of the color in such small quantities that it can be consumed without risk of injury or harm then, in such quantities, it is harmless. A person is as unharmed after consuming a minute harmless quantity of Red 32 (if such there be) as he had he consumed none of it.

"*In United States v. Lexington Mill & Elevator Co., supra,* the Supreme Court reviewed the condemnation of a lot of flour to which had been added a poisonous ingredient, but in a quantity so small that the health of a consumer could not be thereby injured. The statute then provided that an article of food should be deemed to be adulterated if it 'contain any added poisonous or other added deleterious ingredient which may render such article injurious to health'. It was contended there, as it is contended here, that it is the character—not the quantity—of the added substance which is to determine the case. This contention was rejected. The Court said:

> "'If it cannot by any possibility, when the facts are reasonably considered, injure the health of any consumer, such flour, though having a small addition of poisonous or deleterious ingredients, may not be condemned under the Act.' (232 U. S. 399, at 411).

"As in the *Lexington Mill case,* it was held in the Seventh Circuit that 'injurious' is a relative rather than an absolute term. *W. B. Wood Mfg. Co. v. United States,* 7 Cir. 1923, 286 F. 84. We think 'harmless' is also to be so construed." (R. 179-180).

On the issue of fact, that is, whether F&DC Red No. 32 is harmless for use in coloring oranges, the Fifth Circuit Court held:

"The Secretary would concede, apparently, the possibility that a person might consume Red 32 in such small quantities that no hazard to health would result. His guarded statement is that 'the evidence so far available does not establish a likelihood of injury to man from the minute amount likely to find its way into the human diet from the consumption of such colored oranges at the level of use involved.' *The Commissioner of Food and Drugs has admitted that there was no evidence of injury to consumers of colored oranges.* The Secretary has made no effort to ascertain whether or not there is, in fact, any likelihood of injury to the health of persons who consume oranges colored with Red 32. Taking the position that no quantitative test is authorized, the Secretary disclaims any power to fix a tolerance for the use of Red 32 in the coloring of oranges or for any other particular use. Under this theory it would make no difference whether or not there was a minimum quantity of Red 32 which would not be injurious. Malum in uno, malum in omnibus, is the departmental canon of construction.

"*Unless the quantities of Red 32 used in the coloring of oranges are dangerous to public health, the objects and purposes of the Act will not be promoted by a construction which prohibits that use in such quantities.* The statute which we construe provides for the fixing of tolerances for added poisonous and deleterious substances in the production of food and, by a 1954 amendment, for the fixing of tolerances for poisonous pesticides on raw agricultural commodities. *We cannot see how the ob-*

jects and purposes of the statute would be furthered by a construction which permits safe, i. e., harmless, quantities of poisons other than coal-tar colors to be added to food where required in its production, and which permits safe tolerances of poisons for pesticides, but prohibits the use of a coal-tar color in the most minute and harmless quantity because it is harmful and injurious in large quantities. Such a construction would be an unwarranted discrimination, not so much against the coal-tar color and the manufacturers of it, but against that important segment of the orange producers who are economically dependent upon it. The construction of the Secretary results, or may result, in inequality and an injustice. There is, we think, a more reasonable interpretation of the Act." (Emphasis supplied).

We submit that the Court of Appeals of the Fifth Circuit was correct.

Reply To Petitioner's Brief

Since our foregoing brief was written, we have received copy of Petitioner's brief and now append our reply to a few of the statements therein which are not in accord with the record.

Re par. at p. 9, beginning: "The Secretary refused to reopen":

We respectfully suggest that another reason why the Secretary refused to reopen the Hearings and allow the citrus industry its day in Court may very well have been that a principal witness for Respondent would, necessarily, have been Mr. Walter G. Campbell, Chief of F&DA from 1933 until 1944, whose testimony re allegations recited in Petition to reopen and in Exceptions (R. 116-119; 125-130) could have

wrecked F&DA's contention that Congress used the word "harmless" in its most absolute sense, since Mr. Campbell was Departmental spokesman for the legislation from 1933 until enactment in 1938. (See statement of Secretary Wallace, before Committee, December 7, 1933, Dunn, 1049-1050).

Re Footnotes 12, *Petitioner's Brief p.* 34:

The "mottling" of Easter Egg colors was not mentioned in the Order published in the Federal Register. The reference to 1934 seizure of uncertified house paints used for coloring Easter eggs, is irrelevant, that situation having been cured by Sec. 402 (c) of the 1938 Act.

The pertinent fact is that *whatever the reason for restricting the use of "lakes" to the coloring of Easter eggs, such use was so restricted* and the Regulations contemplated that other colors might be similarly restricted to one usage on one food — *but the Secretary has flatly refused to accord to colors used for coloring oranges an equality of treatment with colors certified for use in coloring Easter eggs.*

Re Footnote 20,, *p.* 47 *of Petitioner's Brief*:

F & D A's contention that the word "harmless" should be construed in its absolute sense, was rejected by the June, 1956, report (p. 17) of the *ad hoc* Advisory Committee of the National Academy of Sciences-National Research Committee, appointed, on F&DA's request, to review F&DA's Research Program on Coal-Tar Dyes, to which Report the Secretary refers in this foot note. That Committee said:

. . . "This committee feels compelled to indicate that *certification of a compound as 'harmless and suitable for use' in foods,* drugs and cosmetics as required under the present law *is unrealistic unless*

the level of use is specified. Under a rigid interpretation of this directive many components of ordinary diet could not be certified. *Attempts by FDA to conform to such idealistic standards of absolute safety serves to direct research along unproductive lines. In practice it is possible to certify many useful compounds only on the assumption that they will be used in customary concentrations.* However, a manufacturer might assume that he may safely incorporate in his product any quantity of a certified dye. FDA will continue to be handicapped in setting up a sound research program designed to determine the safety of colors for human use and consumption so long as it is denied authority under the law to specify levels of use . . ." (Emphasis supplied).

The Committee, of course, merely assumed that the 1938 Act does not authorize the fixing of tolerances for coal-tar colors used in food, which we have shown to be incorrect. (pp. 62-65 supra).

Re stätement at p. 2 of Petitioner's brief:

"The Secretary could not borrow the criteria (for tolerances) from Sec. 406 (a), because toxic colors are neither required in production nor unavoidable in good manufacturing practice." (Parenthetical matter supplied).

This is an amazing statement. There are thousands of foods, beverages and confectionaries that are colored, daily, by various certified coal-tar colors. None of these colors are "harmless" in the absolute sense of the word, all requiring tolerances for arsenic, lead and heavy metals, fixed under Sec. 135.02, and for other deleterious substances under Sec. 135.03, of Coal-Tar Color Regulations (21 C.F.R. 135, part 9). Coal-tar colors are used for one purpose only — to improve "eye-appeal" and, thereby, the marketability of the

product so colored. If the Secretary's statement re use of coal-tar colors for coloring oranges, without tolerances, as above quoted, is correct, then it is likewise true that the use of coal-tar colors in such foods, beverages and confections is "neither required in production nor unavoidable in good manufacturing practice."

Yet F&DA continues to certify daily, all coal-tar colors used in the production or manufacture of such articles, where the color is consumed in toto, while refusing to certify Red 32, equally "harmless", for use in coloring oranges, where the color-containing peel is seldom eaten.

We respectfully submit that such discrimination by F&DA against the coloring of oranges — one item from a list of thousands of foods similarly colored, for the same purpose, — constitutes a deplorable abuse by the Secretary of the powers vested in him by the Act, equalled only by his refusal to accord to colors necessary for coloring oranges, found by the Congress to be an "economic necessity" to a great industry, an equality of treatment with colors used for coloring Easter eggs. (p. 34 supra).

Re Footnote 21, p. 48 of Petitioner's Brief:

This is, of course, an insinuation that artificially colored oranges carry far more color in the peel than the 4 ppm reported.

This record discloses (R. 141) that F&DA is itself responsible for the use of the figure of 4 ppm. as being the amount of color found in the peel of an orange.

Re Petitioner's Sec. III, pp. 44-49.

The Secretary's brief, per above and elsewhere, stresses the burden allegedly improperly placed upon the Secretary by the Court below, of bearing the bur-

den of proof that coal-tar colors are, in fact, harmful to human health, before delisting said colors.

This argument ignores the fact that the industry has already once borne the burden of proof that the colors are harmless, by complying with the rigid requirements of Sec. 135-14 of F&DA's Coal-Tar Color Regulations (App. 17-18) (at a cost in a recent case of some $170,000.00; p. 19 supra) following which the data thus submitted was rechecked by F&DA and a regulation promulgated listing the colors as certifiable.

The Secretary is now the proponent of another regulation seeking to delist certain colors on the list. Sec. 7 (c) of Administrative Procedures Act (5 U.S. C.A. 1006) reads in part:

> "(c) . . . Except as statutes otherwise provide the proponent of a rule or order shall have the burden of proof . . . "

CONCLUSION

1. This cause presents two primary issues, one of law, to-wit: the meaning of the word "harmless", and one of fact, to-wit, whether or not FD&C Red No. 32 is harmless and suitable for use in coloring oranges.

2. The language of the 1938 Act, the legislative history of said Act and the previous administrative interpretations all conclusively demonstrate that Congress intended the word "harmless" to be construed in its relative sense.

3. The Secretary admits that F&DC Red No. 32 is harmless in the amounts used for the coloring of oranges.

4. The 1938 Act does not prohibit the Secretary from certifying coal tar colors for limited purposes or

from prescribing the amounts of such color for such purposes.

5. The Congress took special note of the need of the citrus industry for coal tar colors and made special provisions therefor.

6. It is evident from the record in this case that absent an express prohibition in the 1938 Act against the Secretary certifying coal tar colors for limited or specific purposes, there is every reason why the Secretary should make such certification.

7. The judgment of the Court of Appeals of the Fifth Circuit should be affirmed.

Respectfully submitted,

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Of Counsel for Respondent
Frank R. Schell

J. Lewis Hall
Tallahassee, Florida
Of Counsel

CERTIFICATE OF SERVICE

I hereby certify that on this 10th day of October, A. D., 1958, I have served two copies of the foregoing brief on each of the following persons, mail, postage prepaid:

Honorable Arthur S. Flemming,
Department of Health, Education and Welfare,
Washington, D. C.

Honorable J. Lee Rankin,
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Honorable Malcolm Anderson,
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Tampa, Florida
October 10, 1958

APPENDIX

Reprinted from *The Journal of Pharmacy and Pharmacology*, 1956, 8, pp. 417–424

CHRONIC TOXICITY STUDIES ON FOOD COLOURS

PART II. OBSERVATIONS ON THE TOXICITY OF FD&C GREEN NO. 2 (LIGHT GREEN SF YELLOWISH), FD&C ORANGE NO. 2 (ORANGE SS) AND FD&C RED NO. 32 (OIL RED XO) IN RATS

BY M. G. ALLMARK, H. C. GRICE AND W A. MANNELL

From the Food and Drug Laboratories, Department of National Health and Welfare, Canada

Received January 10, 1956

THIS paper describes further studies on the chronic toxicity of food colours. In Part I of this series some chronic effects of Oil Yellow AB and OB in rats were reported[1]. It has previously been reported by other workers that some colours belonging to the azo and triphenylmethane classes caused tumours to develop in animals after subcutaneous injections[2,3]. As some of these colours are being used in food it was thought worthwhile to examine them for chronic oral effects in rats. The effects of the oral administration of FD&C Green No. 2, FD&C Orange No. 2 and FD&C Red No. 32 on growth, food consumption, food efficiency, blood hæmoglobin, and on the pathology of a number of organs are presented in this paper.

METHODS

The methods employed were similar to those reported for the two yellow colours[1]. The food colours were incorporated in the laboratory diet in the following concentrations: FD&C Green No. 2, 0·03, 1·5 and 3·0 per cent; FD&C Orange No. 2 and FD&C Red No. 32, 0·03, 0·75 and 1·5 per cent. The rats were approximately five to six weeks of age at the start of the experiment. The animals were kept in groups of two to a cage and were given free access to their respective diets and water. Their body weight and food consumption were recorded weekly. For more accurate evaluation of food consumption it would have been preferable to place only one rat in a cage, but this was not possible. Post-mortem examinations were made where possible on rats which died on test. All surviving rats were killed at the end of the experiments and post-mortem examinations were made. Many of the organs were weighed and prepared for histological examination. As a result of an unfortunate accident at the end of the fourth week to the male rats on a dietary concentration of 1·5 per cent. FD&C Green No. 2, data on these rats are not included.

RESULTS AND DISCUSSION

The Effect on Growth Rate, Food Consumption and Food Efficiency

Growth, food consumption and food efficiency curves for the groups receiving the various dietary concentrations of the three colours are shown in Figures 1 and 2. Growth rate, food consumption and food

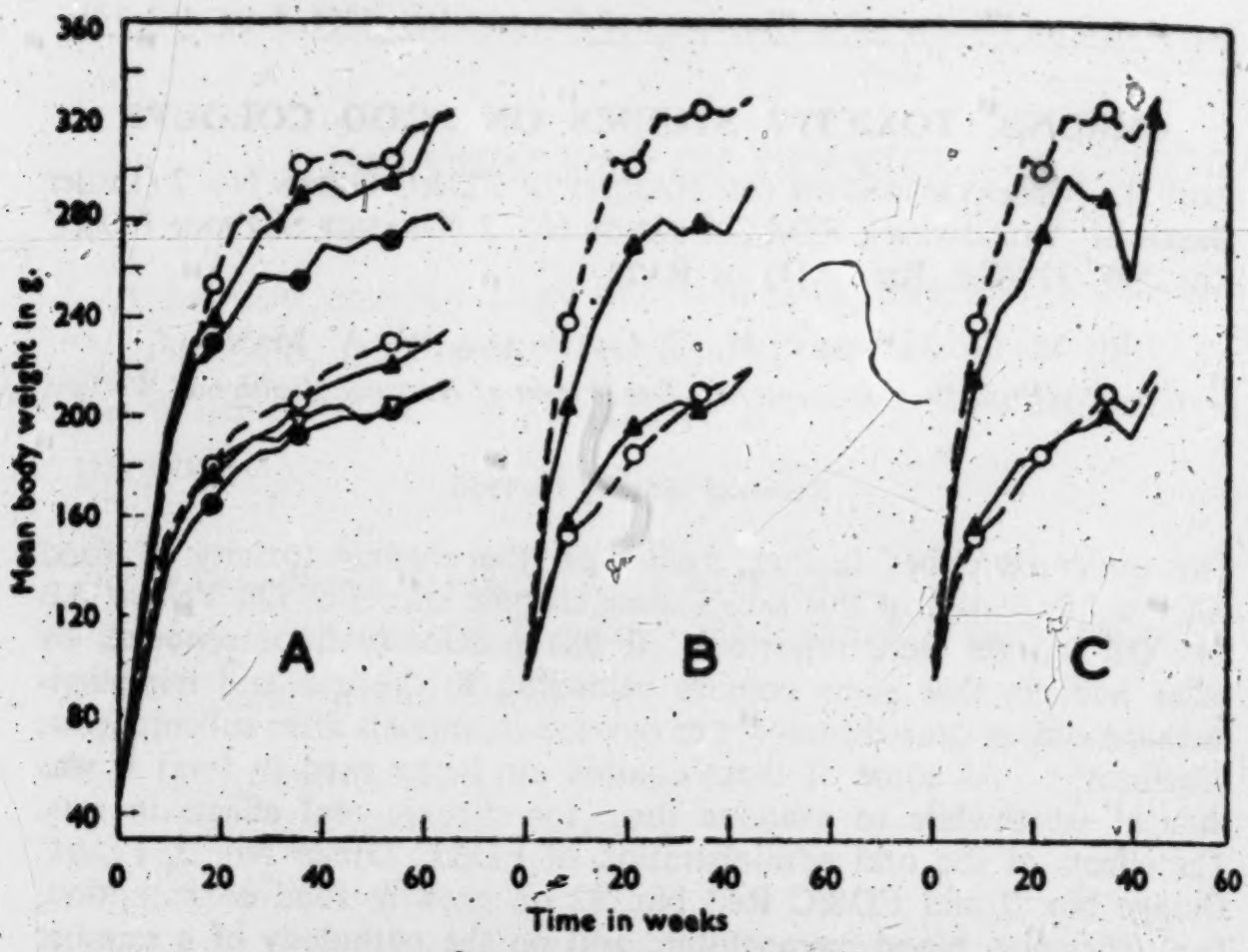


FIG. 1. Growth rate curves for control rats and those receiving the colours. Lower curves are for female rats and upper curves for male rats.

A. FD&C Green No. 2: B. FD&C Orange No. 2: FD&C Red No. 32

○ control; ▲ 0·03 per cent.; ▽ 1·5 per cent.; ● 3·0 per cent.

efficiency were not significantly affected by any of the three colours at the 0·03 per cent dietary level. However, for FD&C Red No. 32 and FD&C Orange No. 2 at the higher concentrations of 0·75 and 1·5 per cent. of the diet, growth rate, food consumption and food efficiency were noticeably affected and all rats in these two groups died before completion of the experiment. For FD&C Green No. 2, two dietary levels, 0·03 and 1·5 per cent. had no effect on growth rate, food consumption or food efficiency, but the 3·0 per cent. level noticeably affected growth rate. This may have been partly due to the amount of food consumed, which was somewhat reduced on this dietary amount. Daily doses of 200 mg./kg. and 400 mg./kg. of FD&C Red No. 32 and FD&C Orange No. 2 for 20 weeks to rats affected growth, food consumption and food efficiency, as shown in Tables I and IV.

The Effect of Mortality

At the end of the test period (65 weeks) the mortality of rats on FD&C Green No. 2 ranged from 52 to 68 per cent. for the respective groups, as shown in Table II. The control group mortality was 68 per cent. The mortality for the respective groups on dietary concentrations of FD&C Green No. 2 was not significantly different from the control. For the other two colours there was 100 per cent. mortality at the 0·75 and

TABLE I

SUMMARY OF DATA ON MORTALITY, FOOD CONSUMPTION AND FOOD EFFICIENCY WHEN FOOD COLOURS WERE GIVEN BY STOMACH TUBE FOR 20 WEEKS

Dose	Sex	No. rats on test	Mortality	Food consumption g./rat/day	Food efficiency g. gain/g. food consumed × 100
Control	M	10	0	13·2	5·2
	F	10	0	11·1	4·7
200 mg./kg./orally/daily ..	M	10	6	12·5	2·9
FD&C Red No. 2 ..	F	10	0	12·7	3·1
200 mg./kg./orally/daily ..	M	10	6	13·9	3·3
FD&C Orange No. 2 ..	F	10	2	10·3	4·5
400 mg./kg./orally/daily ..	M	10	5	12·1	1·7
FD&C Red No. 32 ..	F	10	3	10·1	1·8
400 mg./kg./orally/daily ..	M	10	6	10·3	1·9
FD&C Orange No. 2 ..	F	10	6	10·0	0·6

1·5 per cent. levels by the time the experiment was ended as shown in Table III. By the end of 20 weeks all the rats on the 1·5 per cent. level of FD&C Red No. 32 had died, and at the end of 40 weeks all the rats on the 0·75 per cent. level had died. It was not possible to make autopsies on all the animals which died during the experiment, but the tissues and organs of many of those dying on the 0·75 and 1·5 per cent. dosage were stained with the colours. The kidneys were soft, dark and swollen. The spleen was enlarged and dark in colour. The picture was one of acute toxæmia.

TABLE II

CUMULATIVE NUMBER OF DEATHS

Concentration of colour in diet	Sex	No. Rats on test	Time in weeks on test														
			1	3	5	10	15	20	25	30	35	40	45	50	55	60	65
FD&C Green No. 2																	
Control	M	25	1	6	7	8	10	11	12	13	14	14	14	14	14	16	17
	F	25	0	1	1	2	3	3	3	6	6	7	8	8	8	8	10
0·03 per cent.	M	25	0	0	0	1	1	2	4	8	8	8	8	9	11	13	14
	F	25	0	0	0	0	1	4	4	5	6	7	9	11	12	13	13
1·5 per cent.	F	25	0	0	0	0	1	1	2	2	2	3	5	7	13	13	14
3·0 per cent.	M	25	0	0	2	3	3	3	3	4	10	10	11	11	12	13	16
	F	25	0	0	0	2	2	3	4	6	8	8	9	10	10	14	14

The Effect on Organ Weights

Organs of surviving rats were weighed at the termination of the test. The mean weights (in mg./g. of body weight) are shown in Table IV. The mean weights of a number of organs deviated significantly from those of corresponding controls. Heart, liver, spleen, kidneys and testes were the organs chiefly affected. In very few instances where increases or decreases in organ weights occurred was it possible to demonstrate pathological changes; the changes demonstrated in the testes are an exception. In a number of cases the organ weights were about the

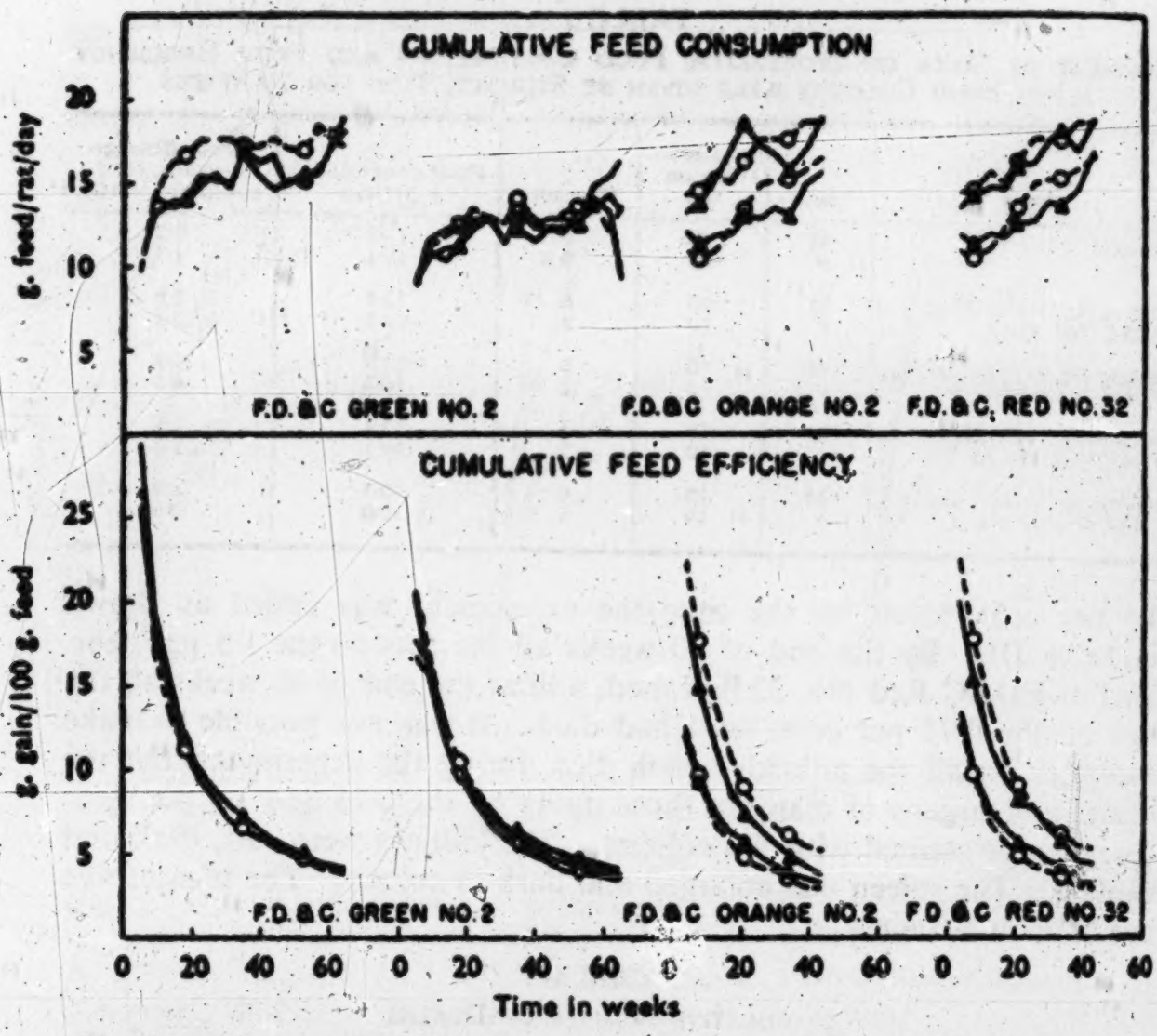


FIG. 2. Food consumption and food efficiency curves for control and test rats, male and female. For FD&C Green No. 2, values for males are shown on the left. For the other two colours, the upper curves represent male rats and the lower curves female rats.

○ Control; ▲ 0·03 per cent., ▽ 1·5 per cent., ● 3·0 per cent.

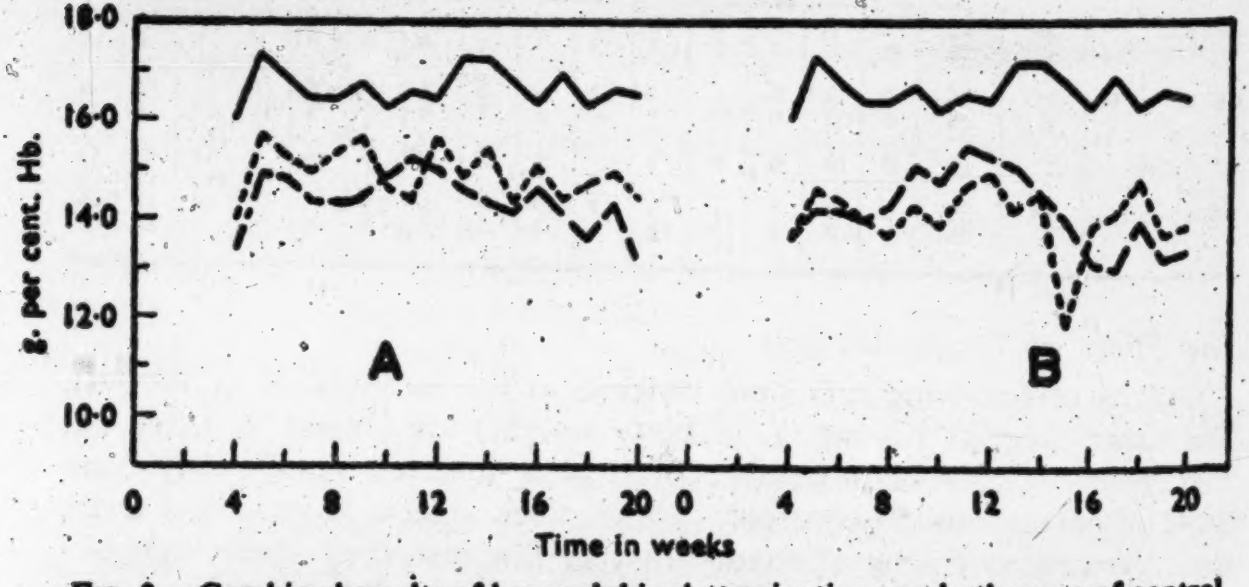


FIG. 3. Combined results of hæmoglobin determinations on both sexes of control rats and those given the two colours at different doses. A. F.D.&C. Red No. 32. B. F.D.&C. Orange No. 2.

— Control: - - 200 mg./kg./rat, oral: — — 400 mg./kg./rat oral.

same as the controls but the body weights of the test animals were less than the controls, suggesting the possible utilization of muscle protein. In other cases the body weights of test and control animals were about the same but the organ weights differed significantly. The changes observed in the organs in these cases appeared like compensatory changes. These results do not demonstrate a correlation of organ weight and the histopathological changes except with the testes.

TABLE III

CUMULATIVE NUMBER OF DEATHS

Concentration of colour in diet	Sex	No. Rats on test	Time in weeks on test											
			2	4	8	12	16	20	24	28	32	36	40	44
FD&C Red No. 32														
Control	M	20	0	2	3	4	5	7	10	11	11	12	13	13
	F	20	0	0	2	2	3	6	7	7	7	7	7	7
0·03 per cent.	M	20	0	0	2	3	3	7	9	9	9	9	16	18
	F	20	0	0	1	1	5	5	6	6	6	6	8	9
0·75 per cent.	M	20	2	3	4	11	15	15	15	16	17	19	20	
	F	20	0	0	0	9	11	13	15	15	15	16	20	
1·5 per cent.	M	20	2	8	11	17	19	20						
	F	20	0	2	10	18	19	20						
FD&C Orange No. 2														
Control	M	20	0	2	3	4	5	7	10	11	11	12	13	13
	F	20	0	0	2	2	3	6	7	7	7	7	7	7
0·03 per cent.	M	20	0	0	1	2	4	6	6	7	8	9	13	13
	F	20	0	0	0	0	1	2	3	4	5	6	7	7
0·75 per cent.	M	20	2	5	10	17	20							
	F	20	3	6	10	17	19	20						
1·5 per cent.	M	20	3	12	17	20								
	F	20	4	10	16	20								

Hæmatology

Hæmoglobin determinations were made weekly for 20 weeks on groups of male and female rats, 10 rats to a group, given daily oral doses of 200 mg./kg. and 400 mg./kg. respectively of FD&C Red No. 32 and FD&C Orange No. 2. A slight modification of the pyridine-hæmochromogen method of Rimington was used[4]. The combined results of these determinations on both sexes are shown in Figure 3, and the mean values of the final determinations are shown in Table IV. The combined blood hæmoglobin values for both sexes show a significant decline in all groups on both colours. This trend was also evident from an examination of the data obtained on each sex.

Blood hæmoglobin values were also determined on the surviving rats from the other experiments. These values, also shown in Table IV, were about the same as those for the controls.

Histopathology

A detailed examination was made of the hæmatoxylin-eosin stained paraffin sections of a number of organs including lung, heart, liver,

TABLE IV

Comprehensive Summary of Observations on Rats fed FD&C Red No. 32, FD&C Orange No. 2 and FD&C Green No. 2

Product	Dosage	No. weeks on test	No. rats surviving / No. rats on test	Mean body weight g. ± s.e.		Mean Hg (g. per cent.) ± s.e.†	Mean organ weight, mg./g. rat ± s.e.					
				Initial	Final		Heart	Liver	Kidneys	Adrenals	Spleen	Testicles
Males												
Control		44	7/20	97·7±5·1	329·1±26·3	15·8±0·29	3·3±0·08	28·6±1·57	6·4±0·07	0·08±0·007	2·4±0·13	8·8±0·35
FD&C Red No. 32	0·03 per cent. of diet	44	2/20	98·4±6·3	330·0± 6·0	16·1±0·75	3·6±0·05	37·0±4·45	7·0±1·20	0·09±0·007	2·6±0·15	8·9±0·73
FD&C Orange No. 2	0·03 per cent. of diet	44	7/20	94·1±5·8	269·4±24·9	15·3±0·50	3·4±0·03	32·5±3·31	7·2±0·13	0·11±0·013	2·4±0·22	8·4±0·63
Control		20	4/10	118·7±5·7	251·0±11·0	17·3±0·40	3·6±0·05	34·9±1·55	7·6±0·25	0·09±0·005	2·5±0·28	9·7±0·38
FD&C Red No. 32	200 mg./kg./day	20	4/10	113·1±4·8	155·0±18·9*	14·1±0·81*	4·6±0·35*	38·2±0·95	9·5±1·55	0·15±0·038*	2·9±0·60	9·6±1·32
FD&C Red No. 32	400 mg./kg./day	20	5/10	115·7±6·4	160·2±14·0*	12·8±1·50*	4·7±0·38*	53·1±2·96*	9·6±0·71*	0·13±0·014*	4·5±0·44*	9·6±1·65
FD&C Orange No. 2	200 mg./kg./day	20	4/10	115·9±4·0	200·0±18·6*	14·1±0·40*	4·1±0·32	44·4±4·46	8·8±0·73	0·12±0·014	4·5±0·52*	11·0±0·70
FD&C Orange No. 2	400 mg./kg./day	20	4/10	110·7±4·0	152·8± 8·6*	13·8±0·64*	4·2±0·18*	44·8±1·59*	8·9±0·49	0·12±0·006	5·0±0·14*	12·9±0·47*
Control		65	8/25	45·6±2·7	323·4±20·0	17·2±0·35	3·2±0·11	30·3±1·01	6·2±0·19	0·08±0·008	2·7±0·26	8·6±0·40
FD&C Orange No. 2	0·03 per cent. of diet	65	11/25	45·5±2·7	323·8±10·9	16·6±0·19	3·4±0·07	32·6±0·82	6·1±0·12	0·08±0·004	2·6±0·11	6·5±0·38
FD&C Green No. 2	3·0 per cent. of diet	65	9/25	45·4±2·7	274·0±12·5*	16·0±0·25*	3·4±0·10	34·9±2·14	6·9±0·38	0·09±0·005	2·3±0·15	5·0±0·69*
Females												
Control		44	12/20	91·7±3·5	219·8± 4·9	15·9±0·22	4·1±0·06	35·7±0·80	7·4±0·21	0·21±0·007	3·4±0·36	
FD&C No. 32	0·03 per cent. of diet	44	11/20	91·8±2·7	214·1± 2·9	14·9±0·66	4·2±0·15	39·2±1·38*	8·1±0·27	0·23±0·010	3·9±0·64	
FD&C Orange No. 2	0·03 per cent. of diet	44	11/20	95·1±3·4	219·4± 5·8	15·6±0·22	4·2±0·13	37·8±1·36	7·8±0·18	0·24±0·011	3·6±0·15	
Control		20	9/10	93·0±3·9	166·9± 6·5	15·7±0·65	4·5±0·41	37·5±1·38	8·2±0·45	0·26±0·031	3·1±0·33	
FD&C Red No. 32	200 mg./kg./day	20	10/10	92·3±4·0	147·6± 5·8*	14·7±0·23	4·5±0·18	43·0±1·73	8·7±0·34	0·20±0·004	4·3±0·15*	
FD&C Red No. 32	400 mg./kg./day	20	7/10	91·6±3·5	124·9± 4·6*	13·4±0·45*	5·0±0·18	51·8±1·92*	9·6±0·14	0·16±0·007*	6·5±2·05	
FD&C Orange No. 2	200 mg./kg./day	20	8/10	88·8±3·3	153·6± 3·1	13·7±0·19*	4·3±0·07	40·2±1·34	7·8±0·30	0·17±0·011	5·6±0·27*	
FD&C Orange No. 2	400 mg./kg./day	20	4/10	89·9±4·0	102·8±11·2*	12·9±1·37*	5·0±0·31	55·1±5·14*	9·9±0·43	0·20±0·022	5·3±0·73*	
Control		65	15/25	39·6±2·4	227·9± 3·9	16·0±0·19	4·1±0·07	35·4±0·84	7·0±0·18	0·22±0·008	3·6±0·13	
FD&C Green No. 2	0·03 per cent. of diet	65	11/25	39·4±2·4	236·7± 6·9	16·4±0·30	3·9±0·09	31·9±1·05*	6·6±0·21	0·21±0·011	3·2±0·06*	
FD&C Green No. 2	1·5 per cent. of diet	65	11/25	39·6±2·3	213·6± 8·7	16·1±0·33	3·6±0·06*	24·4±0·39*	6·1±0·13*	0·16±0·017*	2·7±0·20*	
FD&C Green No. 2	3·0 per cent. of diet	65	11/25	39·7±2·4	210·6± 7·3*	16·0±0·21	4·3±0·12	34·9±1·16	7·3±0·17	0·19±0·005*	3·6±0·22	

* significant at P = 0·05

† determination on 5 rats

TABLE V

Summary of Histopathological Findings

Sex / Dose	Control	Control	FD&C Green No. 2	FD&C Orange No. 2	FD&C Red No. 32	Control	Control	FD&C Green No. 2	FD&C Orange No. 2	FD&C Red No. 32	Control	FD&C Green No. 2	Control	FD&C Green No. 2	Control	FD&C Green No. 2	Control	FD&C Orange No. 2	FD&C Red No. 32	Control	FD&C Orange No. 2	FD&C Red No. 32	Control	FD&C Orange No. 2	FD&C Red No. 32	Control	FD&C Orange No. 2	FD&C Red No. 32
	Male 0·03 per cent. in diet					Female 0·03 per cent. in diet					Female 1·5 per cent. in diet		Male 3·0 per cent. in diet		Female 3·0 per cent. in diet		Male 200 mg./kg./day			Female 200 mg./kg./day			Male 400 mg./kg./day			Female 400 mg./kg./day		
Number of rats on test	25	20	25	20	20	25	20	25	20	20	25	25	25	25	25	25	10	10	10	10	10	10	10	10	10	10	10	10
Number of survivors	8	7	11	7	2	15	7	12	13	11	15	11	8	9	15	11	4	4	5	9	8	10	4	4	5	9	4	7
Number of rats examined	5	5	6	7	2	4	7	6	11	10	4	6	5	8	4	6	4	4	4	6	8	10	4	4	5	6	4	6
Duration of test-weeks	65	44	65	44	44	65	44	65	44	44	65	65	65	65	65	65	20	20	20	20	20	20	20	20	20	20	20	20
Bladder parasites			3	4	1	1		2	2	3		2		3		1												
Hydronephrosis						2		1	1	1						2					1							
Chronic glomerulonephritis						1															1							
Pyelonephritis																										1		
Interstitial nephritis																										1		
Altered spermatogenesis				1										7										1	3			1
Necrotic casts in testes tubules														6														
Ovary fibroma									1																			
Ovary cystadenoma									1																			
Perioophoritis																1												
Liver necrosis														1														
Lung papilloma																										1		
Purulent pericarditis																										1		1
Laryngeal abscess																1												
Acute tracheitis							1																					

spleen, thyroid, pancreas, stomach, small intestine, kidney, urinary bladder, adrenal, testes, ovaries and thymus. A summary of the findings is given in Table V. There were no consistent histopathological changes observed in the tissues or organs studied that could be attributed to the toxic effects of the colours with the possible exception of testicular change which was observed in animals on the higher dietary concentrations. These findings were particularly noticeable in rats on dietary levels of 3.0 per cent. FD&C Green No. 2 and in those receiving daily oral dosage of 400 mg./kg. of FD&C Red. No. 32. On the 3.0 per cent. level of the green colour testicular change was a constant finding. In seven out of eight animals there was tubular atrophy and incomplete spermatogenesis. The change, although constant, was variable in degree. In some testes a few tubules showed complete absence of spermatogenic cells and in others the spermatogenic cells were greatly reduced. Several tubules in each testis contained deep-blue-staining caseous necrotic casts. Remnants of sperm were present in the necrotic debris. The spermatogenic cells and the supporting network of the tubules were undergoing varying degrees of degenerative changes. In some tubules it was apparent that the necrotic casts were being formed from the degenerating cells.

SUMMARY

1. FD&C Orange No. 2, FD&C Red No. 32 and FD&C Green No. 2 in concentrations of 0.03 per cent. in the diet did not affect growth, food consumption or food efficiency in either male or female rats.

2. In groups receiving FD&C Orange No. 2 and FD&C Red No. 32 in concentrations of 0.75 and 1.5 per cent. in the diet, there was 100 per cent. mortality before the completion of the experiment.

3. FD&C Green No. 2 in a concentration of 3.0 per cent. in the diet adversely affected the growth rate which may have been due in part to the amount of food consumed. At the 1.5 per cent. concentration in the diet of female rats no effect on growth rate, food consumption or food efficiency was observed.

4. Haemoglobin production was not affected by 0.03 per cent. in the diet of either FD&C Orange No. 2 or FD&C Red No. 32, but oral doses of 200 and 400 mg./kg. of these two colours caused a decline in haemoglobin values which was significant in both sexes at 20 weeks. Haemoglobin values were not affected by any of the dosage levels of FD&C Green No. 2.

5. The only significant pathology was found in the testes of those rats receiving a dietary level of 3.0 per cent. of FD&C Green No. 2, or an oral dosage of 400 mg./kg. of FD&C Red No. 32.

The authors wish to acknowledge the technical assistance of Miss Elizabeth Carmichael, Miss Elaine Connell and Miss Rita Carioto.

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Excerpts From

S.R.A., F.D.C. 3 Issued September 1940

Federal Security Agency

FOOD AND DRUG ADMINISTRATION

SERVICE AND REGULATORY ANNOUNCEMENTS

Food, Drug, and Cosmetic No. 3

COAL-TAR COLOR REGULATIONS

INTRODUCTION

This publication contains the text of the regulations, promulgated under authority of the Federal Food, Drug, and Cosmetic Act of 1938, for the listing of coal-tar *colors which are harmless and suitable for use in food, drugs, and c o s m e t i c s, and* certification of batches of such colors.

Included are lists of coal-tar colors for use in food, drugs, and cosmetics; in drugs and cosmetics and externally applied drugs and cosmetics, as well as specifications for the *identity and purity to which these colors must conform* in order to be certified.

This publication also contains regulations covering certification of mixtures of certified colors with or without harmless diluents, fees for the certification service, and other information pertinent to carrying out a system of certification as provided by sections 406 (b), 504, 604, and 706 of the Act. (Emphasis Supplied).

Paul V. McNutt, *Administrator*,

Washington, D. C., August 27, 1940.

* * *

GENERAL SPECIFICATIONS FOR STRAIGHT COLORS (p. 3).

* * *

Section 135.02 *General specification for straight Colors.*

No batch of a straight color listed in section 135.03, 135.04, or 135.05 shall be certified under these regulations unless—

(a) It is free from all impurities, (other than those named in paragraph (b) or in the specifications set forth in such section for such color) to the extent that such impurities can be avoided by good manufacturing practice.

(b) It conforms to the following specifications:

(1) In the case of a straight color listed in section 135.03—

Lead (as Pb), not more than 0.001 percent.

Arsenic (as As^2O^3), not more than 0.00014 percent.

Heavy metals (except Pb and As) (by precipitation as sulfides), not more than trace.

(2) In the case of a straight color listed in section 135.04 or 135.05—

Lead (as Pb), not more than 0.002 percent.

Arsenic (as As^2O^3), not more than 0.0002 percent.

Heavy metals (except Pb and As) (by precipitation as sulfides), not more than 0.003 percent.

(3) In the case of a straight color which contains a barium salt listed in section 135.04 or 135.05.

Soluble barium (in dilute HCI) (as $BaCl^2$), not more than 0.05 percent.

STRAIGHT COLORS — FOODS, DRUGS AND COSMETICS

Section 135.03 *List of straight colors and specifications for their certification for use in food, drugs, and cosmetics.*

(a) A batch of a straight color listed herein may be certified, in accordance with the provisions of these

regulations, for use in food (subject to the restrictions prescribed by subsection (c) hereof), drugs and cosmetics, if such batch conforms to the requirements of section 135.02 and to the specification herein set forth for such color.

* * *

FD&C Orange No. 1 (p. 5)

SPECIFICATIONS

Monosodium salt of 4-p-sulfophenylazo-1-naphthol.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 0.3 percent.

alpha-Naphthol, not more than 0.1 percent.

Chlorides and sulfates of sodium, not more than 4.0 percent.

Mixed oxides, not more than 1.0 percent.

Orange II, not more than 5.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 85.0 percent.

FD&C Orange No. 1 (p. 5).

SPECIFICATIONS

1-o-Tolylazo-2-naphthol.

Volatile matter (at 100° C.), not more than 0.5 percent.

Sulfated ash, not more than 0.3 percent.

Water soluble matter, not more than 0.3 percent.

Matter insoluble in carbon tetrachloride, not more than 0.5 percent.

o-Toluidine, not more than 0.05 percent.

beta-Naphthol, not more than 0.05 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 98.0 percent.

Melting point, not less than 128.0° C.

FD&C Red No. 32 (p. 6).

SPECIFICATIONS

1-Xylylazo-2-naphthol.

Volatile matter (at 100° C.), not more than 0.5 percent.

Sulfated ash, not more than 0.3 percent.

Water soluble matter, not more than 0.3 percent.

Matter insoluble in carbon tetrachloride, not more than 0.5 percent.

Xylidine, not more than 0.1 percent.

beta-Naphthol, not more than 0.05 percent.

m-Xylidine in xylidine obtained by reduction of the dye, not more than 30.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 97.0 percent.

Boiling range of xylidine, obtained by reduction of the dye, 95 percent between 212-232° C.

* * *

FD&C Yellow No. 1 (p. 7)

SPECIFICATIONS

Disodium salt of 2,4-dinitro-1-naphthol-7-sulfonic acid.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 0.2 percent.

Ether extracts, not more than 0.1 percent.

Chlorides and sulfates of sodium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Martius Yellow, not more than 0.03 percent.

Pure dyle (as determined by titration with titanium trichloride) not less than 85.0 percent.

FD&C Yellow No. 2

SPECIFICATIONS

Dipotassium salt of 2,4-dinitro-1-naphthol-7-sulfonic acid.

Volatile matter (at 135° C.), not more than 10.0 percent.

Ether extracts, not more than 0.1 percent.

Chlorides and sulfates of potassium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Martius Yellow, not more than 0.03 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 85.0 percent.

FD&C Yellow No. 3

SPECIFICATIONS

1-Phenylazo-2-naphthylamine.

Volatile matter (at 80° C.), not more than 0.2 percent.

Sulfated ash, not more than 0.3 percent.

Water soluble matter, not more than 0.3 percent.

Matter, insoluble in carbon tetrachloride, not more than 0.5 percent.

Intemediates, not more than 0.05 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 99.0 percent.

Melting point, not less than 99° C.

FD&C Yellow No. 4

SPECIFICATIONS

1-o-Tolylazo-2-naphthylamine.

Volatile matter (at 80° C.), not more than 0.2 percent.

Sulfated ash, not more than 0.3 percent.

Water soluble matter, not more than 0.3 percent.

Matter insoluble in carbon tetrachloride, not more than 0.5 percent.

Intermediates, not more than 0.05 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 99.0 percent.

Melting point, not less than 120° C.

* * *

LAKES (p. 8)

Any lake made by extending on a substratum of alumina, a salt prepared from one of the water soluble straight colors hereinbefore listed in this subsection by combining such color with the basic radicle aluminum or calcium.

SPECIFICATIONS

Ether extracts, not more than 0.3 percent.

Soluble chlorides and sulfates (as sodium salts), not more than 2.0 percent.

Inorganic matter, insoluble in HCI, not more than 0.5 percent.

Intermediates, not more than 0.1 percent.

(b) Each lake made as prescribed under the caption "Lakes" in subsection (a) shall be considered to be a straight color and to be listed therein under the name which is formed as follows:

First, the listed name of the color from which the lake is prepared;

Second, the name of the basic radicle combined in such color; and

Third, the word "Lake."

(For example, the name of a lake prepared by ex-

tending the aluminum salt prepared from FD&C Orange No. 1 upon the substratum would be FD&C Orange No. 1—Aluminum Lake.)

(c) No lake listed in subsection (a) shall be certified for any use in food except external application to shell eggs.

* * *

MIXTURES WHICH MAY BE CERTIFIED (p. 35)

Section 135.06 *Mixtures which may be certified.*

(a) A batch of a mixture which contains no straight color listed in section 135.04 or 135.05 may be certified, in accordance with the provisions of these regulations, for use in food (subject to the restrictions prescribed in subsection (d) hereof), drugs, and cosmetics, if—

(1) each coal-tar color used as an ingredient in mixing such batch is from a previously certified batch and such color has not changed in composition in any manner whatsoever since such previous certification, except by mixing into such batch of mixture;

(2) each diluent in such batch of mixture is harmless and suitable for use therein; and

(3) no diluent (except resins, natural gum, pectin and in the case of mixtures which are aqueous solutions or aqueous pastes, sodium, benzoate in a quantity of not more than 1/10 of 1 percent) in such mixture is a non-nutritive substance, unless such mixture if for external application to shell eggs, *or for use in coloring a food specified in the requests for certification of such batch* submitted in accordance with section 135.08 (c), and such diluent, in the usual process of manufacturing such food, is removed and does not become a component of such food.

* * *

(d) No mixture which contains a lake listed in sec-

tion 135.03 shall be certified for any use in food except external application to shell eggs. (Emphasis supplied).

CERTIFICATION (p. 38).

Section 135.09 *Certification.*

(a) If the Food and Drug Administration determines, after such investigation as it considers to be necessary that—

(1) A request submitted in accordance with section 135.08 appears to contain no untrue statement of a material fact;

(2) in the case of a stright color, such color conforms to the specifications set forth therefor in sections 135.02, 135.03, 135.04, and 135.05;

(3) in the case of a mixture containing a diluent, such diluent is harmless and suitable for use therein; and

(4) the batch covered by such request otherwise appear to comply with these regulations,

the Food and Drug Administration shall issue to the person who submitted such request a certificate showing the lot number assigned to such batch and that such batch, subject to the terms, conditions, and restrictions prescribed by section 135.10, is a certified batch for use in food, drugs, and cosmetics, or for use only in drugs and cosmetics, or for use only in externally applied drugs and cosmetics, as the case may be.

* * *

LIMITATIONS OF CERTIFICATES (p. 39).

Section 135.10 *Limitations of certificates.*

* * *

(i) If a coal-tar color from a batch containing any lake listed in section 135.03 is used in coloring any food except shell eggs, such color so used shall be con-

sidered to be from a batch that has not been certified in accordance with these regulations.

LABELING (p. 40)

Section 135.11 *Labeling.*

(a) The label on each package of coal-tar color from a batch that has been certified in accordance with these regulations shall bear, in addition to other words, statements, and information required by or under authority of the Act to appear on such label—

* * *

(4) in case such batch was certified for use only in drugs and cosmetics, the statement *"Not for use in coloring food"*; or in case such batch was certified for use only in externally applied drugs and cosmetics, the statement *"Not for use in coloring food, or in coloring any drug or cosmetic used internally or on the lips or any mucous membrane"*; or in case such batch is a mixture containing a diluent permitted by clause (3) of section 135.06 (a) only because such diluent does not become a component of a food colored by such mixture, the statement *"Not for use in coloring any food except_____"* (the blank to be filled in by the name of such food); or in case such batch contains any lake listed in section 135.03 or any diluent permitted by clause (3) of section 135.06 (a) only because such batch is for use in coloring shell eggs, the statement *"Not for use in coloring any food except shell eggs."*

PROCEDURE FOR ADMITTING COLORS TO LISTING (p. 42)

Section 135.14 *Procedure for admitting colors to listing.*

(a) An application for the admission of a coal-tar color to listing in section 135.03, 135.04, or 135.05 shall be accompanied by—

(1) full reports of investigations which are adequate to show whether or not such color is harmless and suitable for use in food, drugs, and cosmetics, or in drugs and cosmetics, or in externally applied drugs and cosmetics, as the case may be;

(2) a full statement of the percentages and compositions of the pure dye and all intermediates and other impurities contained in such color;

(3) a full statement showing the identity, purity, and quantity or proportion of each intermediate and other article used as a component of such color, and all steps in the process used for the manufacture of such color;

(4) a full description of practical and accurate methods of analysis for the quantitative determination of the pure dye and of all intermediates and other impurities contained in such color;

(5) a full description of practical and accurate methods for the identification of such dye in food, drugs, and cosmetics colored therewith, or in drugs and cosmetics colored therewith;

(6) a five-pound sample of such color (unless the Food and Drug Administration authorizes or requires submission of other quantity suitable to the need for investigation) taken from a batch produced under practical manufacturing conditions, and accurately representative of such batch; and

(7) the advance deposit prescribed by section 135.15 (b) (2).

(b) If the Administrator determines, after such investigation as he considers to be necessary, that—

(1) such color is harmless and suitable for use in food, drugs, and cosmetics, or in drugs and cosmetics, or in externally applied drugs and cosmetics,

(2) practical and accurate methods of analysis exist for the quantitative determination of the pure dye and all intermediates and other impurities contained in such color; and

(3) practical and accurate methods exist for the identification of such dye in food, drugs, and cosmetics colored therewith, or in drugs and cosmetics colored therewith,

the Administrator, for the purpose of listing such color in scetion 135.03, 135.04, or 135.05, shall proceed with a proposed amendment to these regulations as prescribed by section 701 (e) of the Act.

(c) If the Administrator, after such investigation as he considers to be necessary, determines that such coolr does not comply with the requirements laid down by paragraph (b) of this section with respect to procedure for the purpose of listing such color in section 135.03, 135.04, or 135.05, the Administrator shall give notice thereof to the aplicant, stating the respects in which such color does not so comply.

FEES (p. 43).

* * *

(b) (1) The fee for the service provided by these regulations, in the case of each application for the admission of a coal-tar color listing in section 135.03, 135.04 or 135.05, shall be the cost incurred by the Agency in making the investigations contemplated by section 135.14 (b) and (c).

(2) Such application shall be accompanied by an advance deposit of $500 to cover such fee, and thereafter advance deposits of the same amount (unless the Food and Drug Administration authorizes deposit in other amount) shall be made whenever necessary to prevent arrears in the payment of such fee. Any ex-

cess advance deposit so made shall be returned to the applicant after the close of such investigation.

APPENDIX (p. 44)

List of Colors

LIST OF COLOR NAMES SPECIFIED IN THE REGULATIONS AND FORMER NAMES OF SUCH COLORS

Group I.—Certifiable For Use in Food, Drugs and Cosmetics:

Listed as	*Formerly known as*
FD&C Blue No. 1	Brilliant Blue FCF.
FD&C Blue No. 2	Indigotine.
FD&C Green No. 1	Guinea Green B.
FD&C Green No. 2	Light Green SF Yellowish.
FD&C Green No. 3	Fast Green FCF.
FD&C Orange No. 1	Orange I.
FD&C Orange No. 2	Orange SS.
FD&C Red No. 1	Ponceau 3R.
FD&C Red No. 2	Amaranth.
FD&C Red No. 3	Erythrosine.
FD&C Red No. 4	Ponceau SX.
FD&C Red. No. 32	Oil Red XO.
FD&C Yellow No. 1	Naphthol Yellow S.
FD&C Yellow No. 2	Naphthol Yellow S—Potassium salt.
FD&C Yellow No. 3	Yellow AB.
FD&C Yellow No. 4	Yellow OB.
FD&C Yellow No. 5	Tartrazine.
FD&C Yellow No. 6	Sunset Yellow FCF.

GENERAL LABELING REQUIREMENTS FOR COAL-TAR COLORS (p. 53).

The labeling requirements for coal-tar colors are found in part in the Food, Drug, and Cosmetic Act itself and in part in the coal-tar color regulations. The label should contain.

* * *

(7) In the case of a color certified only for a limited use, a statement setting forth this limitation. (Color Regulations: Sec. 135.11 (a) (4).).

U. S. DEPARTMENT OF
HEALTH, EDUCATION, AND WELFARE
Food and Drug Administration
Washington 25, D. C.

FOR RELEASE

Wednesday, November 16, 1955 HEW-C81

The Food and Drug Administration today removed three widely used coal-tar dyes from the list of approved coloring materials which may be added to foods.

The order, effective immediately, was signed by Secretary of Health, Education, and Welfare Marion B. Folsom under the Food, Drug, and Cosmetic Act. The law requires that food colors be certified as completely harmless.

FDA Commisssioner George P. Larrick said the three colors involved are harmless in the amounts ordinarily consumed in foods, but recent scientific investigation shows they are not harmless when fed in large amounts.

The colors involved are FD&C Orange No. 1, FD&C Orange No. 2, and FD&C Red No. 32. Orange No. 1 has been widely used in candy, cakes, cookies, carbonated beverages, desserts and meat products, especially hot dogs. Orange No. 2 and Red No. 32 are the dyes which have been used in coloring the outer skin of oranges.

While manufacturers will no longer label and sell

these three colors for food use they may label and sell them for external drug and cosmetic use. In the future the colors will be identified as Ext. D&C Orange No. 3, Ext. D&C Orange No. 4, and Ext. D&C Red No. 14. The order announcing the change is the final version of a regulation based on evidence received at a hearing held in December 1953.

For many years the certification of coal-tar colors was carried on as a voluntary arrangement between the industy and the Goverment. Certification became mandatory when the Food, Drug, and Cosmetic Act of 1938 was passed. Under the law manufacturers of coal-tar colors routinely submit a sample from each batch to the Food and Drug Administration laboratories in Washington for testing to determine whether they meet required standards of purity. The law requires all coal-tar food colors to be "harmless and suitable for use in food."

U. S. DEPARTMENT OF
HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

Washington 25, D. C.

CORRECTION

Please correct Release HEW-C81, dated November 16, 1955. Make second paragraph read as follows:

"The order is effective 90 days after publication in the Federal Register of November 16, 1955. It was signed by Secretary of Health, Education, and Welfare Marion B. Folsom under the Food, Drug, and Cosmetic Act. The law requires that food colors be certified as completely harmless."

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NO. 27

IN THE

Supreme Court of the United States

OCTOBER TERM, 1958

MARION B. FOLSOM, (now FLEMING),
SECRETARY OF HEALTH, EDUCATION
AND WELFARE,

Petitioner,

vs.

FLORIDA CITRUS EXCHANGE, et al

and

FRANK R. SCHELL,

Respondents

BRIEF OF STATE OF FLORIDA AS AMICUS CURIAE

RICHARD W. ERVIN
Attorney General
State of Florida
Tallahassee, Florida

IN THE

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BRIEF OF STATE OF FLORIDA AS AMICUS CURIAE

Comes now the State of Florida by its appropriate legal representative, the Attorney General, and files this brief as Amicus Curiae, and if leave is required respectfully requests the Court to grant leave to file this brief.

INTEREST OF STATE OF FLORIDA

The production of oranges and citrus fruit is one of the largest industries in the State of Florida, employing large numbers of people and requiring large investments of capital, and large sums of money are invested in the packing houses and coloring rooms and equipment used in the coloring of mature oranges otherwise meeting the standards for grade and pack provided by law. At the time of the hearing

which subsequently resulted in taking FD&C Red No. 32 off the list of certified colors, neither the Florida Citrus Commission nor the Industry itself thought that FD&C Red No. 32 as used in the coloring of oranges was under attack. It had been in use prior to the passage of the Food, Drug and Cosmetic Act of 1938 and had been certified after extensive hearings and had been extensively used without any complaint for around twenty years. It is the only color now used for the coloring of oranges and it is now being used for that purpose only.

The notice of the hearings which resulted in taking FD&C Red 32 off the list of certified colors was inadequate to apprise the Citrus Industry that there was any contemplation of denying its use in the coloring of oranges and there was not sufficient time for the preparation of any defense. The denial of the use of this color at this time would result in great loss to the growers of citrus fruit in Florida and make it difficult, and in some instances impossible, to market fruit which is fully mature and good. The coloring of oranges is an economic necessity and is necessary in the production of fruit for marketing.

ARGUMENT

The State feels that the general factual situation and the law have been covered in the briefs of the Respondents and adopts the arguments set forth in the Brief of Florida Citrus Exchange. The State urges that the construction of the word "harmless" should be construed in a reasonable manner, taking into consideration the uses and quantities of the color used in the coloring of oranges. This construction was properly upheld in the Court of Appeals for the Fifth Circuit. Under the present construction placed

upon the word "harmless" by the Secretary of Health, Education and Welfare it will be impossible to certify any coal-tar color.

Carrying our part of the spirit of Public Law No. 672, 84th Congress, 2d Sess (H.R. 7732), research has been continued and a color developed with 50 times the no-effect level of FD&C Red 32 which in effect provides a color that the amount likely to be ingested is so unfinitesimal that a human being would feel the effects of too much liquid and suffer from the overindulgence of pure juice or an equal amount of pure water before getting enough color to cause injury; in other words man doesn't have the capacity to drink enough juice to ingest enough color to harm him. This new color cannot be certified under the present construction of the Secretary. Certainly we feel that neither the Congress nor the Court intended such construction of the word "harmless" and we respectfully ask this Honorable Court for a construction of the word "harmless" in such a manner that any new coal-tar color which causes no harm except at extremely high levels can be certified.

In view of the reference to the Citrus Commission in Petitioner's Brief, appearing on page 7 of the Petitioner's Brief, we felt that we should appear and, under the provisions of Paragraph 4, Rule 42 of the Rules of the Supreme Court of the United States, we thought it proper for the State of Florida to appear as the Florida Citrus Commission is a State Agency and this brief, as friend of the Court, is on behalf of this agency and the State.

It was not intended that anything that was said by the Florida Citrus Commission should be intended to acquiesce

in or consent to the taking of FD&C Red 32 off the approved list, until another color could be certified which could be used in the coloring of oranges.

To show the importance of the use of color in the State of Florida we include herewith excerpts from the Report of the Florida Citrus Inspection Bureau showing the percentage of color-added oranges since the 1938-1939 season:

Table #1

Season	Oranges Total Shipped	Oranges Total Colored	Percent Colored
1938-39	27,726,963	14,951,080	53.9
1939-40	18,954,443	6,672,269	35.2
1940-41	22,904,429	7,770,624	35.9
1941-42	21,183,713	8,442,970	38.9
1942-43	28,452,013	11,073,757	38.9
1943-44	32,752,390	18,735,188	57.2
1944-45	26,013,918	16,341,691	62.8
1945-46	27,836,857	21,249,972	76.3
1946-47	30,061,266	21,731,995	72.3
1947-48	25,146,951	17,101,488	68.0
1948-49	28,302,233	20,576,590	72.7
1949-50	20,449,442	14,497,245	70.9
1950-51	21,474,494	14,901,864	69.4
1951-52	26,979,133	17,542,648	65.0
1952-53	22,224,392	13,753,552	61.9
1953-54	24,115,727	15,693,140	65.1
1954-55	22,574,267	13,537,175	60.0
1955-56	20,946,070	13,806,103	64.3
1956-57	19,305,133	12,235,129	63.4

The coloring of oranges is not used to conceal inferiority or for deception. The State of Florida and the Citrus Com-

mission have fought for high standards. As pointed out in the Florida Citrus Exchange brief a higher standard of maturity is required before a fruit can be colored than is required on other shipments. The Florida Citrus Code (Section 601) specifically prohibits the use of color for the purpose of deceit. Let us emphasize, the State and the Florida Citrus Commission have worked hard to insure that the public get a good product. Neither would approve or advocate anything to allow an inferior product on the market or to deceive or cover up inferiority.

CONCLUSION

We respectfully submit that this Honorable Court should affirm the decision of the Court of Appeals for the Fifth Circuit and that the matter be so clarified that the Secretary will know that he has the authority to certify coal-tar colors as harmless when in the manner and quantity as used they are harmless.

Respectfully submitted,

STATE OF FLORIDA

By _____
RICHARD W. ERVIN
Attorney General
Tallahassee, Florida

PROOF OF SERVICE

I, Richard W. Ervin, Attorney General of Florida, hereby certify that on the ..... day of ....., 1958, I mailed Air Mail, postage prepaid, five copies of the attached brief to:

HONORABLE J. LEE RANKIN
Solicitor General
Department of Justice
Washington 25, D. C.

HONORABLE WILLIAM W. GOODRICH
Department of Health, Education and Welfare
Washington 25, D. C.

and by regular mail, postage prepaid, five copies of the attached brief to:

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P. O. Box 111
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JAMES R. BROWNING, Clerk

IN THE
SUPREME COURT OF THE UNITED STATES

No. 27.—October Term 1958.

ARTHUR S. FLEMMING, Secretary
of Health, Education and Welfare,

PETITIONER,

vs.

FLORIDA CITRUS EXCHANGE,
FRANK R. SCHELL, et al.

RESPONDENTS.

PETITION OF FRANK R. SCHELL FOR REHEARING JOINED IN BY ALL OTHER RESPONDENTS

MORRIS E. WHITE
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ATTORNEYS FOR RESPONDENT
FRANK R. SCHELL

IN THE
SUPREME COURT OF THE UNITED STATES

No. 27.—October Term 1958.

ARTHUR S. FLEMMING, Secretary
of Health, Education and Welfare,

PETITIONER,

vs.

FLORIDA CITRUS EXCHANGE,
FRANK R. SCHELL, et al.

RESPONDENTS.

PETITION OF FRANK R. SCHELL FOR REHEARING

Frank R. Schell, a respondent herein, respectfully petitions for rehearing of this Court's judgment entered December 15, 1958 and for grounds of this petition, says:

1.

Petitioner filed with the Secretary of Health, Education and Welfare a petition to reopen the cause and proffered additional testimony and evidence that FD&C Red 32 is harmless within the intent and meaning of Section 406(b) of the 1938 Food, Drug and Cosmetics Act. (R. 116-119)

2.

In said petition it was alleged that respondent Schell had no notice of any proceedings to decertify FD&C Red 32 and thereby destroy the Color-Added process, until the formal notice that hearings had been set for January 19,

1954 was published in the Federal Register of December 19, 1953, and that such notice was too late for respondent to employ and inform counsel as to the complexities of the case. (Re. 117-118)

3.

The Secretary denied respondent Schell's petition to reopen the hearings. (R. 118)

4.

The reports of tests run by Food and Drug Administration 1940-1941 and the reports of tests for cumulative or chronic toxicity of FD&C Red 32 over five to six years, 1938-1944, are very sketchily summarized in the exhibits filed by Food and Drug Administration at the hearing (R. 239-240; 240-241; 253-254) but reports of the tests given in 1951-1953 were set forth in great detail in the record. (R. 239-259). By denying petition to reopen the Secretary denied to respondent Schell the opportunity to present and have included in the record full reports of the earlier tests conducted in 1940-1941, which tests resulted in the certification of FD&C Red 32 as harmless.

5.

The report of the tests run by Food and Drug Administration in 1951-1953 contain statements and conclusions that cast serious doubts upon the validity of such tests, for example: "Five of the eleven dogs which had been found to be sensitive to the cathartic action of FD&C Orange 1 was tested on FD&C Orange 2" (R. 239), and the results of the cathartic tests of FD&C Red 32 begins with these words: "Ten of the eleven dogs which had been found to be sensitive to the cathartic action of FD&C Orange 1 were tested on FD&C Red 32". (R. 259)

It was not good pharmacological practice when testing for cathartic action of FD&C Red 32 to use dogs that had been shown to be sensitive to the cathartic action of other coal-tar colors by prior dosages thereof, yet either the five dogs tested with FD&C Orange 2 or five of the ten dogs tested with FD&C Red 32 were being given third cathartic dosages after being found to be sensitive to the first dosage. The five dogs that proved to be sensitive to a dose of but 100 milligrams of the color may well have had four dosages of coal-tar colors, all fed on an empty stomach which would intensify ill effects.

6.

The denial of the petition by the Secretary to grant petition to reopen was urged in the Circuit Court of Appeals, but since the Circuit Court of Appeals reversed the order of the Secretary on other grounds, the propriety of the denial of respondent's petition to reopen was not adjudicated and the propriety of such denial is not adjudicated in the opinion and judgment of the Supreme Court of the United States of date of December 15, 1958.

7.

By denying respondent's petition to reopen the hearings, the Secretary denied to respondent Schell the opportunity of cross-examination and of opportunity to present evidence exposing the inconsistencies in the findings of Food and Drug Administration and the fallacies in the conclusions of Food and Drug Administration as to the validity and meaning of the test conducted by Food and Drug Administration in 1951-1953.

WHEREFORE, respondent Schell respectfully petitions this Court for reargument and rehearing on the matters and things presented herein.

Respectfully submitted,
MORRIS E. WHITE
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OF HALL, HARTWELL & DOUGLASS
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ATTORNEYS FOR RESPONDENT
FRANK P. SCHELL

All other respondents adopt and join in the foregoing Petition for Rehearing, and the undersigned attorney certifies that the same is presented in good faith and not for the purpose of delay.

JAMES HARDIN PETERSON

ATTORNEY FOR FLORIDA CITRUS
EXCHANGE, et al
P. O. Box 111
Lakeland, Florida

CERTIFICATE OF SERVICE

I, J. Lewis Hall, of counsel for respondent, Frank R. Schell, do hereby certify that this Petition for Rehearing is presented in good faith and not for delay and I have on this 31st day of December, A. D. 1958, mailed copies of the Petition to each of the following persons, mail, postage prepaid:

Honorable Arthur S. Flemming
Department of Health, Education & Welfare
Washington, D. C.

Honorable J. Lee Rankin
The Solicitor General
Washington, D. C.

Honorable Malcolm Anderson
Assistant Attorney General
Washington, D. C.

Honorable Beatrice Rosenberg, Attorney
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Honorable William W. Goodrich
Assistant General Counsel
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OF COUNSEL FOR RESPONDENT
FRANK R. SCHELL